BIOTECHNOLOGY AND TECHNOLOGY TRANSFER

HEARING

BEFORE THE

SUBCOMMITTEE ON
TECHNOLOGY AND COMPETITIVENESS

OF THE

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SCIENCE, SPACE, AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

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BIOTECHNOLOGY AND TECHNOLOGY TRANSFER

MONDAY, MAY 6, 1991

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
SUBCOMMITTEE ON TECHNOLOGY AND COMPETITIVENESS,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:03 a.m. in the MCNC Auditorium, Research Triangle Park, North Carolina, Hon. Tim Valentine [Chairman of the Subcommittee] presiding.

Mr. VALENTINE. Ladies and gentlemen, we will try to get started. We have a heavy agenda, a lot of people with a lot of words of wisdom we need to listen to, so that we can find the answers to all the problems that confront us.

I want to say before I make my formal opening statement—to welcome our colleague from California, a distinguished member of our Subcommittee, Mr. Dana Rohrabacher, who represents the 42nd District in the State of California. It is a special pleasure for me to be able to welcome him to North Carolina and to our district and especially to this part of our state.

The competitiveness of American industry is a critical factor in the national security of the United States. As the concept of national security evolves from a focus on military considerations to the economic well-being of the nation, we must look toward new and better ways for American firms to flourish in a new, global marketplace. To remain competitive, companies doing business in the United States must be able to maintain market shares and contribute to economic growth and a high standard of living.

Today, all industry is international. As the old saying—I say old with tongue in cheek—if it does not sell in Denmark, it does not sell in Durham. And I am sure that is familiar to all of you.

[Laughter.]

Mr. VALENTINE. Durham, North Carolina, Durham, New Hampshire, or Durham, England, I suppose.

Technological advancement is one, but not the only important factor in world competition. It is now widely accepted that technology development is responsible for up to one half of the nation's economic growth and is the principal factor in increases in our standard of living. Technology-based sectors generate approximately one-half of the United States gross national product, twice what it was a generation ago.

At the present time, the United States does not have a delineated comprehensive public policy for innovation or for technology de-

velopment. It has been argued that such a Federal policy would be an unwarranted interference in the marketplace. This is, however, in sharp contrast to what most other industrialized societies experience. Even in the absence of a comprehensive strategy, it remains an undisputed fact, however, that what the government does or does not do, influences the private sector and therefore influences of course the marketplace. The various rules and regulations and taxes and other actions of government have become de facto policy as they affect innovation, technology development and industrial enterprise as a whole.

Much of this patchwork of industrial policies was established when the United States was the undisputed industrial leader of the world. We could afford to give more than an even break to our overseas competition. These actions often were taken, not to promote industrial competitiveness, but for a multitude of other legitimate reasons.

Today, times have changed and the United States does not enjoy, as everyone knows, the luxury of pre-eminence in all fields. International competition is tight and market share can be won or lost in an increasingly short period of time.

The ad hoc nature of our technology policy has sometimes led to conflicting regulations and competing practices which have resulted in confusion and uncertainty in the industrial community. The time has come for focused thinking and fresh ideas. If our governments do not listen carefully to our cutting edge companies who do business all over the world, who else will?

Today, we will hear more about these issues from representatives of the biotechnology, the pharmaceutical and the computing and electronic fields. We are fortunate in that we have representatives from both large and small companies. We are also fortunate in that we have representatives from multi-national companies who can present their very special points of view on this problem.

In all these fields, the United States has enjoyed leadership in the international arena; however, in the area of biotechnology, Japan is devoting a considerable amount of private and public resources to improve its capabilities. Germany has instituted a strong governmental research funding agenda and thereby has become a world leader in pharmaceuticals. In the area of high-performance computing, the United States retains a strong lead. The Japanese, however, are quickly closing that gap as well.

I appreciate our distinguished group of witnesses today and we will have them organized. Let me introduce them all at the beginning, we have them organized into pharmaceuticals, biotechnology, high-performance computing and electronics and last but certainly not least under the title "Establishing a Favorable Environment for Technology Transfer".

In pharmaceuticals, we have Dr. Charles A. Sanders, who is President and Chief Executive Officer of Glaxo, Inc.; Mr. Bruce Oberhardt, who is Vice President and Chief Scientific Officer of Cardiovascular Diagnostics, Inc.

In the biotechnology field, we have Dr. Charles Hamner, who is President of the NC Biotechnology Center; Mr. Randall L. Marcuson, President of Embrex, Inc.; Dr. Howard M. Reisner, who is Associate Professor of Pathology, Microbiology and Immunology at

the University of North Carolina at the Chapel Hill School of Medicine and Dr. J. Daniel Lehmann, who is Director of Development, Planning and Administration, Ciba-Geigy Agricultural Biotechnology Research Unit.

In high-performance computing and electronics, Larry D. Huffman, who is Manager of Resource Planning at IBM; Dr. J. Richard Jones, Executive Vice President, BroadBand Technologies and Dr. Larry Lee, who is Vice President for Supercomputing, NC Supercomputing Center.

And in the last category, establishing a favorable environment for technology transfer, we have Mr. James Roberson, President of Research Triangle Park Foundation; Mr. William Riley, Jr., Executive Director, Triangle Universities Licensing Consortium and Mr. Steven Burke, who is Director of Education and Public Affairs, NC Biotechnology Center.

I am happy to recognize at this time for his opening statement or for anything else he cares to do, my good friend, Dana Rohrabacher, who is familiar with our state inasmuch as he served a tour of duty on the coast some years ago, when you were in the custody of your father I believe. Dana.

Mr. ROHRABACHER. Well Mr. Chairman, thank you very much. And first of all, I'd like to congratulate the Chairman for holding these hearings and also for the leadership that he is providing in Washington, D.C. on this very important issue.

As Chairman of the Technology and Competitiveness Subcommittee, Tim is really doing a tremendous job and doing a vital service for our country. Having lived in North Carolina as a young person when my father was in the Marines—I was raised out here in Jacksonville and Cherry Point—I have to say that Tim really exemplifies what I always thought North Carolina was always about. He is forward-looking and he is very hard-working but he is also a lot of fun to work with. So you can be very proud of your Congressman and I am very happy to be here with him.

I am also very pleased to be here in the Research Triangle Park area because it is world famous in terms of its successful integration of basic scientific research with the technology transfer to manufacturing, and therefore it is appropriate, extremely appropriate, that we have this hearing here on biotechnology and technological transfer.

A significant turning point in biotechnological history occurred in 1980 when the United States Supreme Court ruled that a microbe, as developed by General Electric for oil clean-up, could indeed be patented. And six years later patent permit number 4,736,866 was issued for a mouse. And the old saying "build a better mousetrap" has really brought on—a whole new meaning has been brought on when you have mouses that are being invented.

Nevertheless, the field of biotechnology has grown enormously and today the products have the potential of improving almost every aspect of our lives. Consequently, it becomes increasingly important that the results of basic scientific research in this area be transferred to production in a manner that is both effective and efficient.

I look forward to the hearing and look forward to the testimony from today's outstanding witnesses on how we can improve biotechnology and the transfer.

Mr. Chairman, I want to again express my appreciation for your leadership in calling this hearing and the citizens of North Carolina are certainly very fortunate to have you representing them and it is a privilege to be here with you today.

Thank you very much.

Mr. VALENTINE. Thank you, Dana. I will load your vehicle down with that North Carolina barbecue as payment for you saying those good things.

[Laughter.]

Mr. VALENTINE. I would ask first witnesses Dr. Sanders and Mr. Oberhardt if they would come around and have seats. I think we have got Mr. Oberhardt seated here, that is your name and we do not want to confuse and put the right person behind the wrong name or vice versa. We Congressmen do not need any further confusion.

Let me say as they are seating themselves, in addition to the prepared statement which I made, that we—and I am sure that I speak for Dana and other members of the Committee—this is to be more than a verbal exercise today. I am convinced that the leadership of the Science Committee, both the Chairman and the Ranking Republican Member, the leadership on our Technology and Competitiveness Subcommittee from both parties are committed to attempting to address the problem of competitiveness in this country, and reaching, hopefully, some kind of workable formula for getting on with the business of reversing the trend that has and is occurring now. I believe that we have the attention of the leadership in Congress on both sides of the aisle in the House and Senate, the attention of the Administration and I think the attention of American business and industry, that we have to work together to do something about this, what could develop into a catastrophe.

Doctor.

STATEMENTS OF DR. CHARLES A. SANDERS, CHIEF EXECUTIVE OFFICER, GLAXO, INC. AND DR. BRUCE OBERHARDT, VICE PRESIDENT AND CHIEF SCIENTIFIC OFFICER, CARDIOVASCULAR DIAGNOSTICS, INC.

Dr. SANDERS. Thank you, Mr. Chairman, Congressman Rohrabacher, ladies and gentlemen. I am very pleased to be here this morning to talk about the subject of technology and competitiveness, which in my own personal opinion has to rank very near the top of the American agenda for the 1990s.

Before talking about it, however, I would like to just briefly tell you a little bit about Glaxo. Glaxo Inc., is a research-based pharmaceutical company which is headquartered here in Research Triangle Park and it is the United States subsidiary of the London-based Glaxo Holdings p.l.c. Glaxo is one of the largest corporate taxpayers in North Carolina and employs approximately 4400 people here in the Triangle, in Zebulon, North Carolina and throughout the United States.

The success of our research, I think is reflected by the rather extraordinary growth that we encountered during the decade of the 1980s. As a company in the United States, we ranked 69th in 1980. At the end of that decade, 1990, we ranked number four. The company rose from a ranking of some 45th in the world in the late 1970s to second today. This has been the result of an extraordinarily successful research-based program which has yielded innovative products which have contributed very substantially to the benefits of human health.

Now as far as our base here in North Carolina, our tax payments and employees are only two measures of the tremendous growth. And I would just point out the benefits of scientific innovation in bringing us to the point that we have reached today.

We are currently expanding here in the United States our research capability, which is reflected symbolically by the recent opening of a $450 million research facility here in RTP. It is state-of-the-art, it will have some 1200 scientists by the end of 1992 and it is thoroughly and totally committed to doing basic research and clinical development of new medicines, which will benefit society.

Now let me just speak very briefly if I may about some of the points which are included in my testimony and are more fully expanded upon. As it applies to Glaxo Inc., technology transfer is the process by which we develop new chemical entities or so-called NCEs, into the pharmaceutical therapies meeting genuine patient needs. Indeed, if one looks at it, the United States is the biomedical research laboratory of the world, and has been for the last 100 years or so, certainly in the last 50. And of course the major driving force since World War II has been the National Institutes of Health. That has been one of the greatest success stories in any sort of research enterprise and indeed the people who envisioned that and have led it and continue to support it, and notably the Congress, deserve a tremendous amount of credit in putting the United States in the forefront of biomedical research and keeping it there.

Now discovery and development are really at the heart of our entire industry. To be sure, it must be looked at in the following context—basic research is the business of academia. Acquisition of knowledge for the sake of acquiring knowledge is what academia is all about. The basic business of industry, if you will, is development. We do a lot of basic research but not anywhere nearly the profusion or volume that occurs in academic enterprise, specifically NIH and throughout our medical schools and universities in this country.

Industry takes the discovery, the technology and transfers that into a specific product, whether it is in electronics or the pharmaceutical industry, and sells it into the marketplace and as a result of those sales, it is able to fund its continuing research and development program. The point that I would make is that these two enterprises—or three enterprises; academia, government and industry, really are tied together in a way which is synergistic and which is hard to define or quantify in many ways, but is a process which has worked extraordinarily well in the last 50 years.

Now I think that it should be pointed out, and particularly United States industry, has—in pharmaceuticals—has made ex-

traordinary investments in its R&D programs, because that is its lifeblood. If it does not discover any new products, then it does not have any product to sell and there is no industry. It is very simple.

To give you a few facts, from 1976 to 1985, 139 new chemical entities, or NCEs, were introduced in the United States, 49 percent more than Japan, our next closest competitor. Of the 24 NCEs that were introduced in the United States in 1990, seven were developed in the United States and the United Kingdom was next with three. United States companies accounted for 83 percent—83 percent of genetic engineering patents issued in the United States in 1989, establishing our leadership very clearly there. And it should be pointed out that the pharmaceutical industry, since 1988, has been investing more money in R&D than the National Institutes of Health. This year, the pharmaceutical industry collectively in the United States will invest some $9.2 billion in R&D as opposed to nearly $9 billion on the part of the NIH. And it should also be pointed out that the pharmaceutical industry in the United States is one of the very few industries that has a positive trade balance, some $268 million, as opposed to the near $100 billion trade deficit that we are encountering as a nation.[1]

I should point out that the Japanese, as you noted, Mr. Chairman, are challenging the United States for leadership. From 1981 to 1985, they accounted for about 25 percent of the worldwide NCE introductions, about the same as the United States.

Now for the United States to maintain its leadership in technology and R&D development in the pharmaceutical industry in particular, we would welcome mechanisms that would strengthen the following four areas:

First of all, anything that would encourage the government, the academic and industrial partnership.

Second, anything that will enhance incentives for R&D—and I will be more specific about this in a few moments.

Thirdly, do anything to augment the FDA resources for their review of the NCEs or the new medicines.

And finally, do anything that can remove the obstacles to free market forces that allow R&D investment to continue and specifically to protect intellectual property or patent protection.

Now I have elaborated on the first of these; namely, the synergism of the government and the academic and industrial partnership that result in the expansion of the knowledge leading to new medical innovation, but let me give you a very specific example.

Głaxo has, with the University of North Carolina, been involved in a joint research enterprise in a drug called amiloride. Amiloride is a relatively old drug which has been used in the treatment of hypertension in years past but has recently been found to be useful in the treatment of patients with cystic fibrosis, a disease which really does not have any effective treatment. And while this drug does not cure it, it appears to be very useful in terms of ameliorating many of the symptoms and hopefully improving the longevity of these people afflicted with this genetic disease.

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[1]$268 million represents 1988 figures; $100 billion represents 1990 figures.

What we have done is to support the program at UNC, support the research and now have engaged in a relationship whereby we are taking amiloride and developing it under an orphan drug status, its utility in cystic fibrosis. And here is a very good example, I would suggest, of industry supporting research in academia which is then being transferred into the industrial enterprise for clinical development of a product which will ultimately be useful to a very specific population. It also shows very significant benefits of having the orphan drug program, which I have commented upon more fully in my testimony.

The second thing that I would like to comment on is incentives for R&D. R&D is a high-risk, high-cost enterprise with an average development cost in the pharmaceutical industry of $230 million. That figure has been challenged recently. I point out that I think the difference is really more one of accounting rather than substance and I am perfectly happy to stand behind the figure of $230 million to develop one compound to reach the market.

Continued investment in R&D would be greatly encouraged, I might add, by making permanent the R&E, the research and experimentation tax credit, which the Congress has seen fit to expand on a regular basis, albeit temporarily. Our time horizon for developing products is some eight to 12 years and, if you looked at the nine month to 15 month extensions that occur with the R&E in the Congress, it would be, I think, much better policy, public policy, if we could look forward to that on a regular basis rather than worrying or being concerned about whether it is going to be renewed in the next session. I am sure that is reasonably obvious.

I should also point out—just going back to my earlier testimony relative to the cost of developing drugs—that only three in ten of the drugs that reach the market ever recover their investment. And if you go into a laboratory, all kinds of leads will evolve but only one in 4000 ever makes it to the market. So it is just a way of emphasizing the high-risk nature of the enterprise.

The next point I would like to make is that I think, hopefully, the government and the Congress in particular will carefully consider the findings of the so-called Edwards Committee, which is the Health & Human Services Advisory Committee in the FDA. As you know, the FDA is under considerable attack from time to time. Its current commissioner feels that it has lost credibility with the public and with the Congress and is emphasizing enforcement. Suffice it to say, the FDA is being asked to do a great deal more work, just a ball park figure would be twice as much work in the year 1991 than it was in 1985, and it has the same number of people now as it had six years ago. And it vitally needs help. And I would hope that the Edwards Commission recommendations would be very carefully listened to.

And finally, I think that we should recognize, and I am sure we all do, that the free market which we live in has served innovation and American health really pretty well. One cannot emphasize enough, I think, the value-added benefits of medicine. For example—and although this is close to home, it is a very good example—we sell an anti-ulcer medication called Zantac, which heals ulcers miraculously in some four to eight weeks. It avoids surgery, and if you look at the cost-effectiveness of that, it is really rather extraor-

dinary. Surgery will cost anywhere from seven to ten thousand dollars, it is associated with risk, it is associated with morbidity, people may or may not have symptoms afterwards, there is no guarantee that surgery is going to be a great success, and you have taken a risk of undergoing anesthesia and you can have problems post-operatively and on a chronic basis, which are very unpleasant and debilitating. Zantac, which is our anti-ulcer medication, avoids all of these. So it is cost-effective, it is health maintaining, it clearly makes the point that pharmaceuticals give value added and obviously that is what containing health care costs is all about and a source of great concern to all of us.

I will just point out something that is already familiar to you, and that is that the pharmaceutical costs of the health care dollar is really somewhere between six and seven cents of the total. So while we are a rather discrete target, if you will, a discrete target for price control, we are really not the major problem in terms of health care costs.

Suffice it to say that I think as we move along in our search for cost-containment, there will be more and more temptation, I think, to put price controls on various aspects of the health care industry and pharmaceuticals in particular. I hope very much that that will be resisted.

And in closing, I would say that if we in the GATT negotiations can achieve a parity in the intellectual property where the intellectual property of American companies will be recognized and there will not be piracy throughout the world in terms of reproducing our products, then I think that the economy and certainly the trade balance will be served extremely well.

Thank you very much.

[The prepared statement of Dr. Sanders follows:]

CHARLES A. SANDERS, M.D.
CHIEF EXECUTIVE OFFICER, GLAXO INC.

Statement before the
Subcommittee on Technology and Competitiveness
of the House Committee on Science, Space and Technology

May 6, 1991

Mr. Chairman and members of the subcommittee:

My name is Charles A. Sanders, and I am chief executive officer of Glaxo Inc. I appreciate this opportunity to comment on the importance of technology transfer to the pharmaceutical industry.

Glaxo Inc. is a research-based pharmaceutical company with headquarters in Research Triangle Park, N.C., and is the U.S. subsidiary of London-based Glaxo Holdings p.l.c. Glaxo is one of the largest corporate taxpayers in North Carolina and employs 4,400 people in North Carolina and throughout the United States.

Our tax payments and employee base are only two measures of the tremendous growth Glaxo has enjoyed since coming to North Carolina in 1983. At the heart of our growth has been scientific innovation, which through technology transfer we have been able to develop into innovative medicines meeting genuine patient needs.

Glaxo Inc. is currently expanding its research capability in the United States. Symbolic of that effort is the recent opening of our new state-of-the-art research and development center in North Carolina, which represents an investment of $450 million in construction and equipment. By 1992, Glaxo will have 1,200 scientists and research staff working to discover and develop new medicines in its Research Triangle Park facilities.

Glaxo is committed to furthering pharmaceutical research and development in the United States. The U.S. now leads the world in innovative pharmaceutical research, and the contributions of U.S. pharmaceutical researchers show that new ideas in medicine continue to be born at a rapid pace today.

In the decade from 1976 to 1985, 139 new chemical entities were introduced into the United States market, according to a report in Scrip, a highly respected international pharmaceutical newsletter. That figure is over 49% higher than the next closest competitor in this category, Japan. The United States is also the world leader in the discovery of new chemical entities. An analysis also cited in Scrip shows that of the 24 NCEs introduced in the United States in 1990, seven were developed in the United States. The next most frequent country of origin was the United Kingdom, with three. In the emerging field of biotechnology, the Pharmaceutical Manufacturers Association reports that U.S. companies accounted for 147, or 83%, of the genetic engineering patents issued in the U.S. in 1989 for health care and pharmaceutical inventions.

These numbers represent a significant contribution to health. They also represent a significant contribution to the U.S. economy. Amid a multi-billion dollar industrial

trade deficit, the U.S. industry in 1988 had a $268 million positive trade balance.

However, in recent years international competition has intensified, challenging U.S. leadership. Especially notable are the Japanese, who from 1981 to 1986 accounted for around 25% of the worldwide NCE introductions, up from 9% in the period from 1961 to 1970, according to a study by Duke University economist Henry Grabowski. In the same time periods, the percentage of worldwide NCE introductions in the U.S. remained stable, also at about 25%.

For the United States to maintain its position among the world leaders in the development of important new medicines, it is clear that the industry must aggressively pursue methods of technology transfer that are as innovative as the products that result from it. We must try to streamline our drug development processes, to the extent we can do so, while continuing to ensure our products' safety and efficacy. Further, we must continue our efforts to identify innovative ideas.

To that end, we would welcome mechanisms that encourage appropriate collaboration between industry, government and academia. We also would welcome legislative and regulatory reforms that would continue and enhance incentives for R&D investments, that would augment Food and Drug Administration resources devoted to the review of new medicines, and that would respect and remove obstacles to the free market forces that have led to a healthy industry -- and a healthy America -- today.

Government-Academia-Industry Collaboration

The leadership role that the United States has achieved in technological innovations in competitive international markets is in part due to the tradition in this country of collaboration between government, academia and industry.

This research partnership has resulted in a synergistic relationship that is considered the model by other countries seeking to develop national research programs. Through legislation and policy, our federal and state governments have recognized the importance of encouraging the transfer of the results of publicly funded research to the industrial sector.

Glaxo located in Research Triangle Park in large part because of its proximity to major universities. We have established a number of research projects with these and other academic and research institutions, and we believe these collaborative efforts will result in the expansion of scientific knowledge leading to new advances in medicine.

One promising result of this partnership is the development of an inhaled form of the drug amiloride, which shows promise as a possible treatment for cystic fibrosis. We became interested in the drug as the result of research conducted by scientists at the University of North Carolina, and we acquired the rights to develop the drug from them. In conjunction with the UNC researchers and the National Cystic Fibrosis Foundation, we have committed our resources to the development of this drug, an expensive and time-consuming process, and clinical trials are expected to begin soon.

This compound, developed decades ago in another form as a therapy for hypertension, is an example of how research at a

taxpayer-supported university can be augmented by industry. It also stands as an example of the sort of government-academia-industry partnership that Glaxo urges the federal government to continue to support.

Incentives for R&D investment

Pharmaceutical research and development is a high-risk enterprise by any measure. Studies by the Center for the Study of Drug Development at Tufts University show that, on average, taking a single compound from laboratory bench to pharmacy shelf represents an investment of more than $230 million and 12 years. Only one in 4,000 drugs synthesized make it to market. Of those that do, only three in 10 ever recover their development costs.

This year the U.S. industry will increase its R&D investment about 14% to $9.2 billion, a level representing about 17% of total industry sales, the highest R&D-to-sales ratio of any technology-based industry. Glaxo alone will invest about $1 billion worldwide this fiscal year.

In such investments lie the future of the industry, as well as the future of health care. Government is in a unique position to encourage a continued high level of investment by making permanent the tax credits associated with R&D. The fact that the U.S. industry's R&D expenditures have doubled every five years since 1970 demonstrates how this approach has encouraged investments in innovation.

Government similarly should resist weakening the tax incentives and marketing exclusivity associated with the development of orphan drugs, which fill a vital need in patient groups that otherwise would be too small to justify the extraordinary expenses of modern discovery and

development. Since the Orphan Drug Act of 1983 became law, 45 orphan drugs and more than 130 other rare disease medicines have gone into human trials or are at the Food and Drug Administration for review. At Glaxo, amiloride, the cystic fibrosis drug under development, has gained orphan drug status.

Continued R&D investment also is encouraged by intellectual property protection, which allows a pharmaceutical company a fair chance to recoup its development costs and achieve revenues that allow increased research expenditures. Glaxo supports the efforts of Congress and the Bush administration to encourage respect for patents worldwide and urges them to resist any effort, in the United States or abroad, to curtail existing intellectual property rights.

FDA drug review process

Glaxo recognizes the need for a strong and vital Food and Drug Administration and supports federal funding of the agency at a level that will enable it to fulfill its responsibility to protect health and safety.

We also recognize that new responsibilities -- including those resulting from new legislation, increased consumer awareness and the AIDS epidemic, among other factors -- have strained the agency's resources. We further recognize the effects of delayed marketing approvals on the health of the American public and future pharmaceutical innovation.

Glaxo recognizes the importance of the work of the HHS Advisory Committee on the FDA chaired by former FDA commissioner Charles Edwards and urges the government to evaluate carefully the committee's recommendations on reform.

We also urge Congress to support full funding of the FDA and to consider other measures to bolster FDA resources to a level adequate to safeguard the agency's mission of ensuring the safety and efficacy of pharmaceutical products, while shortening the review period of new drug applications.

Obstacles to free market

Glaxo believes that it is no coincidence that the world's leading country in pharmaceutical innovation is also a nation with a free-market economy. The United States' free market encourages innovation by rewarding it, and thereby has created a highly competitive industry in which even the market leader has a market share of less than 8%. The free market promotes an environment that stimulates R&D investment as companies continue to compete to develop a better product. This environment has contributed to the breakthrough medications of the last several decades that are commonplace today.

Such medical advances would be severely threatened, however, if price controls were allowed to effect a fundamental change in market dynamics. Price controls are antithetical to a free market. They threaten the foundation of a vigorous industry that has had an extraordinary record of producing valuable medicines that lower the overall cost of health care. They take responsibility for business decisions out of the hands of those best equipped to make them. Any imposition of price controls would inhibit R&D investment and innovation. Ultimately, patients would be unable to benefit from the advances in medicine they have enjoyed since World War II.

Glaxo urges the government to establish mechanisms to prevent unwarranted intrusions into the free market system that has served this nation's health so well and so long.

Mr. VALENTINE. Thank you, Doctor.

Dr. Oberhardt.

Dr. OBERHARDT. I would like to—that is a difficult act to follow, that was very comprehensive. I would like to add two brief comments; number one, it is Dr. Oberhardt and number two, I am not going to speak about pharmaceuticals, I am going to speak about diagnostics. And the reason is that we are a small diagnostics company. Diagnostics is also a global business. It is complementary to pharmaceuticals. In fact, in diagnostics you answer questions such as how is the patient doing or what is the level of the therapeutic drug. Diagnostics is a business that is tied into getting information.

The segments, the major segments of diagnostics are non-invasive diagnostics and everybody is aware of the x-ray machines, CAT scans, magnetic resonance imaging, electrocardiography. These are all examples of non-invasive diagnostics.

In vivo diagnostics, where one actually invades the body; examples of that would be cardiac catheterization, endoscopy.

And then we have another segment which is the one that we are involved in, which is called in vitro diagnostics or diagnostics conducted on samples away from the body, such as blood analysis. Cardiovascular Diagnostics, our company, or CDI, is involved in the in vitro diagnostics business. Now this segment of diagnostics is today more than $12 billion worldwide at the manufacturer's level, in sales of instruments, reagents and service.

I think it should be pointed out that diagnostics companies require a different and more costly product support network or infrastructure than pharmaceutical companies. Small diagnostic companies do not have this infrastructure and are therefore dependent upon larger companies for marketing, product distribution, product sales, field support and often for manufacturing. Today, many diagnostics companies in this particular $12 billion segment—or $12 billion-plus segment, of the industry are experiencing low profitability due to low revenues and rising costs.

Cardiovascular Diagnostics is a five year old venture-backed company and the focus of CDI is in vitro diagnostics, the cardiovascular arena and decentralized delivery. In other words, performing diagnostic testing away from the laboratory; for example, at the patient's bedside. This is really very highly cost-effective diagnostic medicine and we feel this will ultimately lower health care costs because when you do this you eliminate a lot of bureaucracy and labor associated with testing.

Our company uses research and development to create new diagnostic technology and then to develop this technology into product. We actually are fairly good, for a small company, at converting basic technology into products. We have successfully licensed technology in the form of products to corporate strategic partners on a global basis. We have transferred technology to these strategic partners, we have collected license fees and we are due royalty payments from these partners. And we have also performed a support role to help the partners get into the business.

The research and development that we conduct at our company is mostly internal, using multi-disciplinary people or an approach that is multi-disciplinary. We use many different disciplines. We are helped to a large extent by the use of outside consultants, both

in the industrial sector and also from the university, academic sector. We are highly dependent upon clinical trials at major medical centers and we are also helped to a large degree by research grants such as from the SBIR program, federal program, and also from other sources such as the North Carolina Biotechnology Center grants.

The strengths in general of small companies apply to us; that is, speed and flexibility, the people that make things happen, a high level of creativity and innovation at a relatively low dollar cost and also efficiency in new product development. Some additional strengths that we have as a company are relationships with Research Triangle Park, area universities and other institutions, a proprietary technology and a market niche.

The weaknesses in general of small companies in the diagnostics arena are very limited capital, lack of a complete product support infrastructure and possible lack of the economy of scale for full manufacturing.

I have some general statements regarding what we would see as possible federal government steps to improve technology transfer. This is directed from our smaller company perspective. I have five things.

One is to expand the federal research grant program to universities and the SBIR program to small companies. The possible benefits of this are that you would be creating more technology for transfer, there would be more rapid product development, more rapid technology transfer and increased utilization of inventions by the federal government. In today's rapidly changing technological environment, rapid obsolescence is also a problem and the greater the rate of technology generation, the more fuel there is to supply to the fires of technology transfer.

Secondly, I think it is important to create standards to recognize the uniqueness of small entrepreneurial technology driven companies, to recognize—for example, to create tax regulations that recognize their unique problems, that do not punish these companies. And I think it is important that the business cycle of many of these companies is not a full cycle with cash flow. It is a cycle of development, trying to license and trying to generate enough revenues to create a true business cycle. The present laws do not favor companies of this type and it is very difficult for a company to survive in this environment. And the possible benefits of doing something about this would be more rapid growth, creation of jobs, and improvement of international competitiveness.

Third, the creations of incentives to lower the cost of capital. The possible benefits of this would be more modern plants and equipment, higher efficiencies, greater capacity to use technology and environmental safety.

Four would be for the government to identify and study models for streamlining regulatory activities to move products to the marketplace sooner, to transfer technology with greater certainty of success as a result of streamlining. I would agree also that we need more people involved in the process to do this, particularly on the part of the FDA and other agencies.

And five, to create incentives for companies to participate in the improvement of education at all levels, both in companies, in the

public and private education sectors and particularly in the technology transfer areas. Because if education participation on the part of companies, large and small, could be realized, we would see increased entrepreneurism in the United States. We would have a more educated work force and there would be a greater foundation for future technology transfer.

Thank you.

[The material of Dr. Oberhardt follows:]

Possible Federal Government Steps to Improve Technology Transfer

1. **Expand Federal Research Grant Program to Universities and SBIR Program for Small Companies**

Possible Benefits:

- more technology for transfer
- more rapid product development
- more rapid technology transfer
- increased utilization of inventions by federal government

2. **Create Standards to Recognize the Uniqueness of Small Entrepreneurial Technology Driven Companies and Create Tax Regulations that Recognize their Unique Problems and are not Punitive.**

Possible Benefits:

- More rapid growth, creation of jobs, improvement of international competitiveness.

3. **Create Incentives to Lower the Cost of Capital**

Possible Benefits:

- More modern plants and equipment, higher efficiencies, greater capacity to use technology, environmental safety

4. **Identify and Study Models for Streamlining Regulatory Activities.**

Possible Benefits:

- Moving products to the marketplace sooner, transferring technology with greater certainty of success

5. **Create Incentives for Companies to Participate in Improvement of Education at Company, Public and Private Education Levels, Particularly in "Technology Transfer".**

Possible Benefits:

- Increased entrepreneurism
- More educated work force
- Greater foundation for future technology transfer

CARDIOVASCULAR DIAGNOSTICS, INC. (CDI)
BRUCE J. OBERHARDT, PH.D.

DIAGNOSTICS = INFORMATION BUSINESS

Helps answer questions, such as: How is patient doing? What is therapeutic drug level?

DIAGNOSTICS = GLOBAL BUSINESS

Segments: Non-Invasive Diagnostics; such as electrocardiography and magnetic resonance imaging

In Vivo Diagnostics; such as endoscopy and cardiac catheterization

In Vitro Diagnostics; such as blood analysis

CDI is in the last segment:

In Vitro Diagnostics Business

More than $12 billion segment, worldwide at manufacturer's level (instruments, reagents, service)

Diagnostics companies require a different and more costly product support network or "infrastructure" than pharmaceutical companies.

Small diagnostics companies do not have this infrastructure and are dependent upon larger companies for marketing, product distribution, product sales, field support, and often for manufacturing.

Today, many diagnostics companies in this 12 billion dollar plus industry segment are experiencing lower profitability due to lower revenues and rising costs.

CDI is:

a 5 year old venture backed diagnostics company

CDI FOCUS

- in vitro diagnostics
- cardiovascular
- decentralized

Decentralized = away from lab, e.g. at patients bedside = better healthcare and ultimately lower healthcare costs

CDI uses R&D to:

- create new diagnostic technology
- develop technology into products

CDI has:

- licensed technology (products) to corporate strategic partners
- transferred technology to strategic partners
- collected license fees (and royalty payments) from partners
- performed a support role for its licensees

CDI Research and Development is:

- mostly internal, using a multidisciplinary approach
- helped by the use of outside consultants
  a) industrial
  b) university
- dependent upon clinical trials at major medical centers
- helped by research grants
  a) SBIR Program
  b) NCBC Grants

Small Company Strengths:

- speed, flexibility
- people that make things happen
- high level of creativity and innovation at a relatively low dollar cost
- efficiency in new product development

Additional CDI Strengths:

- relationships with Research Triangle Park Area universities
- proprietary technology
- market niche

Small Company Weaknesses:

- very limited capital
- lack of complete product support system or infrastructure
- possible lack of economy of scale for production

Mr. VALENTINE. Thank you, Doctor.

Dr. Sanders, I do not want to ask you a question that is kind of like which of your children do you love best, but if you—could you list for us what you think is the most important of your four steps which are needed to maintain a positive trade balance?

Dr. SANDERS. I think the most important is really early approval by the FDA. Of all the things that we do, if we do not get our product on the market in a timely way, then we certainly do not realize the benefits from the marketplace, which then feeds back into supporting the R&D.

The FDA, unfortunately, as I indicated, is under-staffed and over-worked. Just to give you a few statistics, which I am sure are very well known, the average length of drug approval in the United States is 32-1/2 months and that is for a new chemical entity. And for—if you compare that with other countries, notably Europe, for example, you are dealing with a drug approval time somewhere between 12 and 18 months. And I am sure we all realize that each month that is lost in the approval process is a month that is lost in terms of sales. And that has very significant impacts on the health of the company and more importantly I think, in getting the drug to the public so it can be used for the purpose it is intended.

Mr. VALENTINE. Early in my Congressional service, as I recall, there were complaints about the patent law and how that affects this industry. Do you see that as an area that still needs substantial reform?

Dr. SANDERS. Well I think that the Waxman-Hatch Act did a fair amount to redress some of those imbalances by giving recognition of the time in the approval process in part to extending the life of the patent. So I do not view that as as big a problem now in the United States as it was previously. Patent protection overseas continues to be a major problem, which is being addressed in the GATT talks. For example, intellectual property protection does not exist in Brazil, although we are assured that that may well occur, Argentina, certain of the Asian countries. But there are major markets in South America that are a very significant problem in this area.

Mr. VALENTINE. Other than making it permanent, do you see a need for other reform in the research and experimentation tax credit that we talked about, other than making it a better deal and making it permanent or making it so that it would result in further tax savings, because of course you know when you get into saving taxes on one hand that reduces the income on the other, and we cannot put those people at FDA in that sort of thing.

Dr. SANDERS. I well understand the limit that one faces. I think the R&E credit is particularly important, particularly to smaller companies. It is important to us, no doubt about that, but as Dr. Oberhardt was saying, they are in a situation where they are on the margin and particularly in the electronics and diagnostics business, where the patent position is very difficult to maintain. You spend a lot of time protecting your patent only to find out that it is too late, the products have gone on past through obsolescence.

I do think at the moment that the R&E definition is pretty strict. I think it is often difficult perhaps to define clearly where experi-

mentation ends and clear development for a product begins, but I think that there still is a little give in there where that could be relaxed, to allow a better arrangement. Perhaps there could be some threshold in terms of sales of a company to give them a more attractive—not a more attractive—but a better arrangement in terms of their tax credits, sort of an escalating scale which would top out at a certain level of research and development expenditure.

I do not know quite the answer to that and that is really off the top of my head, but suffice it to say that I think right now if it could be made permanent, that would be the first thing that should be done because going from Congress to Congress particularly in the business that Dr. Oberhardt is in, it makes it very difficult to enter any sort of long product life cycle.

Mr. VALENTINE. We understand I think the need for intelligent comprehensive intellectual property protection regulations, statutes, but could you just spend another sentence or two to tell us how stronger intellectual property protection would affect the overall picture of technology transfer?

Dr. SANDERS. Well if you do not have intellectual property protection—the best example, I think, Congressman, is there was a compulsory licensing law that Canada followed for many years, that has now changed as a result of some legislation called CS-22 that was passed a couple of years ago. But up until that law, you could bring—an innovative research-based pharmaceutical company would introduce a product in year one and it would have three years of exclusivity in the marketplace. And so it had to build its sales in those three years because after three years the company was required by law to license the patent to a copier, a generic company who would come in, take all of the know-how of manufacturing, get a license to manufacture the product and sell the product. And what would happen is you would see sales of a product go from zero maybe to $30 million and then over the period of the subsequent 18 to 24 months, it would fall back to seven. Now the problem with that, of course, if you look at the cost of developing a product, $230 million, to get a product to market, you just cannot recoup your investment. So it is not only a chilling effect, it would destroy an industry if that were the market in which you had to operate world wide. Fortunately, Canada being only one country, you are able to survive by virtue of being in larger markets where there was patent protection, such as the United States, the UK, Germany and France.

But if that intellectual property protection were not available in the whole, we could not exist as an industry. It is just that simple.

Mr. VALENTINE. I want to yield to my colleague but I have one further question of Dr. Oberhardt.

We hear a lot when we discuss this problem about the cost of capital, interest rates and how that is an advantage at least to Japanese, not just in this area but all areas of competitiveness. Would some form of governmental support for a venture, venture capital loan program—would that help address some of the acute problems which you face as a small businessman, entrepreneur?

Dr. OBERHARDT. That is a very interesting thought. Not having considered that before, I am really not sure of how that might work. But I think that investment in venture capital or creating

incentives for more venture capital is probably a wise thing to do in general. But in terms of how that might work, I am not really clear as to what kind of mechanisms could be developed. I think it is important that when one does make more venture capital available, it is important that the investment structure is intact so that the people who have responsibility to wisely invest these funds do a good job. You do have professional investors and the ones that are out there seem to have capital. The question is if you made much more capital available, would you have the core of professionals readily available to make wise investments, and I am not really—that is out of my area.

Mr. VALENTINE. Dana.

Mr. ROHRABACHER. Mr. Chairman, thank you for giving me this opportunity.

Dr. Sanders, I would like to ask you a question. You just listed several countries that you said were more apt to offer patent protection, but you left out Japan, I noted. Is there a problem in Japan with patent protection?

Dr. SANDERS. No, there is not a problem with Japan in that area anyway. Now it is very hard to get your products on the market there.

Mr. ROHRABACHER. That was my next question. Maybe you could give me a little more briefing about the challenge, Japanese challenge in your area in terms of pharmaceuticals and what the Japanese challenge to our leadership is.

Dr. SANDERS. Well as I alluded to very briefly, they are—the Japanese have been very successful in the discovery and development of new chemical entities and as one looks at the statistics in terms of the numbers, it has been a steadily increasing number since the 1970s. To be sure, I think to put it in balance, there are a number of products that are on the market in Japan, which would not jump the hurdles of the FDA. In their terms of their regulatory agency, they require more the demonstration of safety as opposed to efficacy. The FDA, for example, many years ago, prior to 1962, required only a demonstration of safety and efficacy was not such a big issue.

On the other hand, to get past that, if you go past that, the real issue with the Japanese is two-fold. First of all, is just the entry of a foreign company into Japan. Mr. Pickens I guess found out about buying—trying to buy a share of companies in Japan, that was more than he could handle. But if you look at the success of the pharmaceutical industry in Japan, foreign companies really have not done all that well.

Prior to my coming to Glaxo, I was with a company called Squibb, and its experience is very much the same as Glaxo. Squibb is now of course part of Bristol-Myers, but both Squibb and Glaxo have, through the years, operated their own company, albeit small, a Nippon-Squibb, a Nippon-Glaxo, which ranks 50th in terms of Japanese companies, which is not having much of a presence at all. The only way that the products from the American company, in this case, Glaxo, have been able to make an impact on the Japanese market has been to license your products through an existing Japanese company, a major Japanese company. Sankyo is a major Japanese company who is a licensee of both Squibb and Glaxo now.

And as you try to introduce your products, you find that your ability to develop your own company is limited by a whole host of regulations and laws and culture. And in order to reach the maximum penetration, you have to license to another Japanese company and essentially co-market and compete. You can either co-promote, which means having the same product under the same label, or you can co-market which means having the same product under different labels so you are selling against each other. Depending upon the circumstances, that is usually the format that is developed.

Mr. ROHRABACHER. The prices paid by Japanese consumers for pharmaceuticals, how does that relate to our prices?

Dr. SANDERS. Well it is hard to know. That was my second point that I was going to make. Actually the drug bill in Japan is about 30 percent of the total bill. They have the highest drug bill in the world. Now I just cannot say that—surely they do not have the highest health care bill, they do not have the highest hospitalization bill. I think we in the United States lead the league in that regard. So pharmaceuticals comprise an extraordinary percentage in terms of the Japanese health care bill and what has happened is that the regulatory agency there, the so-called NHI, regularly reduces drug prices so that what happens is you come in with a premium price and you can expect to get these maxi and mini devaluations, much like some of the currencies around the world, that occurs once every year or two, usually every two years, sometimes every year.

Mr. ROHRABACHER. But for the same pharmaceuticals, is the Japanese consumer paying more?

Dr. SANDERS. It is roughly comparable to more, it is not less.

Mr. ROHRABACHER. And the obstacles, the barriers that you find, does that permit Japanese companies then to make money that is then turned around and used to compete with you?

Dr. SANDERS. Yes. It is a self-fulfilling cycle, if you will. The big stay big and the small stay small. It is awfully hard to get an edge up in the marketplace or a leg up in the marketplace if you cannot have a very large market. The barrier to entry is very considerable.

Mr. ROHRABACHER. And in terms of what is going on now with GATT and some of our other negotiations, do you think that some of these problems will be solved or do you just see that this is not going to be solved in the short term?

Dr. SANDERS. Well I think some of the problems will be solved in terms of intellectual property protection in those countries that I alluded to, I have hopes for that. I think the Japanese marketplace will continue to be a very sizable barrier to entry for American companies and certainly for the pharmaceutical industry.

Mr. ROHRABACHER. Thank you very much.

Mr. VALENTINE. Thank you.

One more quick question, or maybe two. Every time we have a session of this kind, it seems to me we get horror stories about what happens to American companies when they try to deal with Japanese and maybe one of these days, Dana, we should get the—we should try to get the overall picture because there must be something we do not understand.

Mr. ROHRABACHER. Maybe we should go to Japan and hold one of these hearings.

Mr. VALENTINE. Maybe so. Could we leave this afternoon?

[Laughter.]

Mr. VALENTINE. Because we just have to look around and look out here in this parking lot to see what the Japanese are doing to the automotive industry. American automobile manufacturers and others who visit in Japan say it is hard to find an American car there. I know they import a lot of agricultural products.

But would you say—you might not want to answer this because I know you to be a diplomat—but would you characterize Japanese practices as moderately or reasonably protective or more raunchy?

[Laughter.]

Dr. SANDERS. Well I think they are extraordinarily protective.

Mr. VALENTINE. All right, sir.

Dr. SANDERS. What I would say, Congressman, if I could just add on, is that I think that we ought to bear in mind that the Japanese have been extraordinarily successful for a very good reason. They produce high-quality products. That is a challenge to American competitiveness on the one hand. The other thing that I think we should bear in mind is that they have had an extraordinary success in two or three areas in the American marketplace, cars being one, electronics being another, cameras being a third. I am sure there are other examples. I also can say that I think this has been part of a national policy on the part of the Japanese government to be successful in these areas around the world. And I have the very distinct feeling, and I can say no more than that, that in the 1990s you are going to see the pharmaceutical industry in the United States targeted, that the Japanese will be more and more of a force. It is not their style for hostile takeovers, but they will be coming more and more into American industry in a variety of ways. They are already doing it in Europe in terms of joint ventures with existing European companies. Fujisawa bought an American company called Lyphomed. There are a number of joint ventures that are beginning to emerge and so I think that you'll see more and more of a Japanese presence in the United States in the pharmaceutical industry in this decade.

Mr. VALENTINE. Could either one or both of you just tell us briefly—and if this, in your opinion, needs more explanation I would encourage you to let us have some addenda to your remarks, to your answers in writing—but Dr. Oberhardt and Dr. Sanders, is there a way that we could streamline, significantly streamline the process while maintaining safety and thorough testing to protect the public?

Dr. SANDERS. Well, you know, I think the best way, Mr. Chairman, is what the current Commissioner is trying to do. He is trying to put some sound management principles embodied in experienced people into the agency. He is trying to give them the appropriate technology to deal with these extraordinarily lengthy and detailed drug applications. It is a daunting task, we will send 150,000 pages—that says something about the bureaucracy we have spawned through the years. But trying to turn that one back is going to be very difficult. So we deal with what we have to deal with. And what I would say is I think that this Commissioner has

his eye on the right targets. And if he is supported by the Congress, then I think that we have a chance to improve the process. I am not looking for a revolution, I do not think that that is possible. But I do think that if we can improve these review times which go to giving him the necessary resources, then I think that we can go a long way.

Mr. ROHRABACHER. Mr. Chairman, if you would indulge me one more question.

Mr. VALENTINE. Certainly.

Mr. ROHRABACHER. You hinted at—not hinted, but you touched on in your testimony that the Japanese in their approval process look only at safety or focus on safety rather than efficacy of the drug. Would it not—do you think that perhaps we should start looking in that—or approaching drug approval in this way? After all, we have got budget problems. And leave it up to the doctor to decide whether or not a drug is effective and the public can have it just as long as it is safe?

Dr. SANDERS. Well that is one approach. As a physician, I do not think I would want to advocate that. Perhaps as a marketing person, I might, but I do think it is up to—in terms of prescription drugs, there really should be a standard showing efficacy, I think that is a standard that we should not discard.

Mr. VALENTINE. Dr. Oberhardt, do you have any answer that—anything you would like to add before I ask Dr. Sanders to leave a case of that ulcer medicine here?

[Laughter.]

Dr. OBERHARDT. Just more generally, in perhaps some of the areas where you have overlapping agencies. And I know there may be others today who will address this. We have more than one agency under whose jurisdiction something may fall. I think that is an area where there could be some streamlining or improvement or by combining efforts to speed processing of applications and so forth.

Mr. VALENTINE. Thank you very much.

Our next panel consists of Dr. Charles Hamner, President of the NC Biotechnology Center; Mr. Randall L. Marcuson, President of Embrex; Dr. Howard M. Reisner, Associate Professor of Pathology at UNC-Chapel Hill and Dr. J. Daniel Lehmann, Director of Development, Planning and Administration, Ciba-Geigy.

Welcome, gentlemen. We appreciate your taking the time to respond to our invitation to prepare yourselves and to come and impart to us your words of wisdom. Your prepared statements will appear in the record as presented to us and we request that you summarize.

Dr. Hamner.

STATEMENTS OF DR. CHARLES HAMNER, PRESIDENT, NORTH CAROLINA BIOTECHNOLOGY CENTER; RANDALL L. MARCUSON, PRESIDENT, EMBREX, INC.; DR. HOWARD M. REISNER, ASSOCIATE PROFESSOR OF PATHOLOGY, MICROBIOLOGY AND IMMUNOLOGY, UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL SCHOOL OF MEDICINE AND DR. J. DANIEL LEHMANN, DIRECTOR OF DEVELOPMENT, PLANNING AND ADMINISTRATION, CIBA-GEIGY AGRICULTURAL BIOTECHNOLOGY RESEARCH UNIT

Dr. HAMNER. Chairman Valentine, Congressman Rohrabacher, I thank you for the opportunity to testify here this morning. What I would hope to do is to say a few words about the Biotechnology Center and some of its key programs and how they relate to development of biotechnology, and indicate that the Center's role is to act as a catalyst, an enabler and a fosterer for development of the biotechnology industry, particularly in North Carolina.

The North Carolina General Assembly in 1981 created the North Carolina Biotechnology Center as the nation's first statewide initiative in biotechnology. There are a large number of biotechnology centers now in about 35 or so states. So biotechnology has been recognized by the states as being something important to their growth and development in the economy. Biotechnology of course is a very broad term that includes a collection of cellular manipulation technologies that are aimed at solving unique biologically based problems in agriculture, health care and the environmental fields. And for that reason, it will have an extremely broad impact on our society. It will touch all of our lives over time.

Of course biotechnology is truly an industry that begins with basic scientific research, usually in a university laboratory. This is an industry that was spawned in the universities. And then of course ends with commercial products developed by industry in large and small companies that we have here represented this morning.

The Biotechnology Center utilizes four programs to undertake the comprehensive approach that it has for developing of the industry, and I will mention four of them.

First is the Center's program to strengthen research capabilities in the state's universities. Of course, biotechnology was spawned in the universities 15 years ago and it requires considerable research funds to carry forth and to enable the university to stay at the leading edge of the technology. Of course the National Institutes of Health, National Science Foundation, USDA to some extent, play a very important role in funding the university research program.

Secondly, we have a biotechnology information program. Now the biotechnology industry is a very dynamic and rapidly growing, rapidly changing industry and it needs assembly and analysis of data for commercial activities and products in order to plan, develop and market the next generation of products. And so our Center provides information to about 50 industrial clients and many federal agencies. The federal government seems to utilize our services extensively. For example, USDA, the EPA, the FDA utilize our services, the White House Office of Science and Technology, the Treasury Department and in the last couple of weeks the Interna-

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tional Trade Commission has been working with us on things that they are gathering information on.

Our third program is a very aggressive education and public affairs program. I think it is true that many people recognize that scientific research is fundamental to the development of biotechnology, but few people I think have recognized that public education and understanding are essential to development of this industry. It's a very pervasive industry, it is going to touch all of our lives through health care, the food we eat, the environment we live in and many of the environmental problems that exist today concerning hazardous waste, oil clean ups and so forth, are going to be resolved through biotechnological remedies.

Mr. Steven Burke is going to say more about the educational programs later, so I am not going to say any more about the educational programs.

But I do want to talk a bit about the fourth program at the Center and that has to do with corporate development. The Center assists companies of all sizes and at all stages of development and promotes technology transfer and collaboration between universities and companies. One of our biggest programs is to try to move technology—try to first help create technologies in the universities and then help move those out into useful products.

The North Carolina Biotechnology Center so far has assisted in the transfer of 16 biotechnologies from four North Carolina universities, and I will just mention two or three.

The synthesis of boronated nucleosides as therapeutic agents from Duke University to Boron Biologicals.

The development of an ultrasensitive ELISA technique to quantify blood clotting factors from Wake Forest University, Bowman Gray School of Medicine to Elcatech Corporation.

The development of a delivery system to poultry embryos in-ovo for biologics, growth and metabolic regulators from North Carolina State University to the Embrex Corporation and we will have talk about that in just a moment.

And then the development of gene-detection instruments from the University of North Carolina-Chapel Hill to Gene-Tech, Inc.

They are some examples of the kinds of technology we are able to assist in the movement of those technologies. In all, the Center has assisted 29 young companies or about an average of six per year, to conduct basic research for new products that have come from various universities, some of them from out-of-state universities who now are in North Carolina companies, and of course we like to encourage that also.

The state biotechnology centers such as North Carolina's are playing a major role in developing the nation's biotechnology industry and infrastructure, particularly the infrastructure programs related to the growing and building of these companies. And the 1990s will be a critical period for development of the industry world-wide. And so those states and regions and countries that provide the right scientific, business, educational and regulatory environments will gain enormously from the industry, and those that do not will fall behind.

Now the federal government I think can further catalyze the industry in several ways.

First, they can provide national attention to better intellectual property protection and a speed up of the patenting process that is so crucial to the industry. I understand there is something like a backlog of around 7000 patents now in the Patent Office in biotechnology.

Secondly, there is much confusion at the federal level about the regulatory process, especially with the USDA and the EPA, pertaining to permits for release of genetically engineered organisms into the environment for field testing during product development. Now certainly some work has been done on this and we have certainly worked closely with USDA and the EPA in developing these kinds of regulations, but it certainly is true that clear, consistent guidelines are essential if agricultural products are going to be developed and agriculture is going to truly benefit from the biotechnology breakthroughs. Such guidelines will instill public trust and public trust is essential to this industry, and give agricultural, chemical and environmental industries a stable and known regulatory climate. This is not necessarily a call for more regulation, but rather a call for clean, clear-cut consolidation of procedures so that the industry knows how to proceed.

Finally, financial assistance programs such as the federal Small Business Innovation Research grant programs like Dr. Oberhardt mentioned awhile back is very important to young biotechnology companies and needs continued support in funding from the Congress.

So in summary, biotechnology is a new and rapidly growing technology. It will have a large impact on the public's well-being and federal efforts to enhance the industry would include at least five things:

Providing research funds to universities.

Assisting biotechnology centers in building the infrastructure, and at this point in time, the biotechnology centers at the state level are taking the leadership in building the infrastructure for the industry.

Enhancing the patent process for new inventions.

Providing clear, consistent regulatory guidelines for product development.

And last, but certainly not least is providing seed funds through the SBIR programs and various business incentives to aid critical early development phases for start-up companies. Start-up companies in this country now hire over 50 percent of the new hirees in this country. So start-up companies are very important to our economy.

I thank you very much for the opportunity to make these remarks.

[The prepared statement of Dr. Hamner follows:]

TESTIMONY BEFORE THE SUBCOMMITTEE ON TECHNOLOGY
& COMPETITIVENESS OF THE HOUSE COMMITTEE
ON SCIENCE, SPACE & TECHNOLOGY
Research Triangle Park, NC - May 6, 1991

BIOTECHNOLOGY TRANSFER AND COMPETITIVENESS

Dr. Charles E. Hamner, DVM, Ph.D., President
North Carolina Biotechnology Center

Mr. Chairman, Members of the Committee; this state's General Assembly, in 1981, created the North Carolina Biotechnology Center as the nation's first statewide initiative in biotechnology. Biotechnology is a broad term that includes a collection of new technologies that use living cells or parts of cells to make new products or solve unique biologically based problems in agriculture, health care, or environmental fields. Biotechnology begins with basic scientific research, usually in a university laboratory, and ends with commercial products developed by industry.

The Biotechnology Center works at all points in the movement of ideas from the research laboratory to the marketplace. The Center utilizes four programs to undertake its comprehensive approach (see Attachment 1).

First, the Center's Scientific Program strengthens the research capabilities of the state's universities:

- Biotechnology, a new and rapidly growing technology spawned in the universities about 15 years ago, requires research funds to enable the universities to stay at the leading edge of competitiveness. Through its grants programs, the Center has committed more than $17 million to improve the research capabilities of North Carolina's universities.

Secondly is our Biotechnology Information Program:

- The rapidly growing biotechnology industry needs assembly and analysis of data on commercial activities and products in order to plan, market and develop the next generation of products. Our Center provides information to over 50 industrial clients and many federal agencies such as the USDA, EPA, FDA, the White House Office of Science and Technology, the Treasury Department and the International Trade Commission (see Attachment 2).

Thirdly, the Center has an aggressive Education and Public Affairs Program:

- While many recognize that scientific research is fundamental to development of biotechnology, few have recognized that public education and understanding are essential to development of the industry.

- Through the Center's secondary education project, high school science and agriculture students are learning about biotechnology and its possibilities as a career opportunity. Community college and undergraduate college programs are training students to be technologists and managers. Newsletters and sponsored events are gaining the attention and support of the adult population. Societal issues are also being carefully considered.

The fourth program is the Center's Economic and Corporate Development Program:

- This program assists companies of all sizes and in all stages of development. It helps entrepreneurs with basic research to develop product ideas, and fosters relationships between larger and smaller firms. It encourages the legal and financial communities to enable and invest in this evolving industry, and it promotes technology transfer and collaborations between universities and companies.

- The North Carolina Biotechnology Center so far has assisted in the transfer of 16 biotechnologies from four North Carolina universities (see Attachment 3). Examples include:

  - Synthesis of boronated nucleosides as therapeutic agents: from Duke University to Boron Biologicals, Inc.
  - Development of an ultrasensitive ELISA technique to quantify blood clotting factors: from the Bowman Gray School of Medicine of Wake Forest University to Elcatech Corporation.
  - Development of a delivery system to poultry embryos in-ovo for biologics, growth and metabolic regulators: from North Carolina State University to Embrex, Inc.
  - Development of a gene-detection instrument: from University of North Carolina-Chapel Hill to Gene-Tech, Inc.

- In all, the Center has assisted 29 young companies, an average of about six per year, to conduct basic research for new products.

As I have just indicated, state biotechnology centers, such as North Carolina's, are playing a major role in developing the nation's biotechnology industry and infrastructure. The 1990's will be a critical period for the development of the industry world-wide. States, regions and countries that provide the right scientific, business, educational and regulatory environments will gain from the industry; those that do not will fall behind. Therefore, federal programs that assist the biotechnology centers will pay a large return on investment and assure a strong competitive position for the United States.

In addition to supporting state biotechnology centers, the federal government can further catalyze this industry in several ways:

- Strong governmental funding of research in agriculture, health care and environmental protection will enhance our standard of living as well as maintain our technology leadership.

- National attention to better intellectual property protection and a speed-up of the patenting process are crucial to the industry. I have read that there is now a backlog of over 7,000 biotechnology patent applications at the patent office and that the average application requires 25 months for approval.

- Also, there is much confusion at the federal level about the regulatory process, especially with the USDA and EPA pertaining to permits to release genetically engineered organisms into the environment for field testing during new product development. Some work has been done on the problems, but clear, consistent guidelines are essential. Such guidelines would instill public trust and give the agriculture, chemical and environmental industries a stable and known regulatory climate.

- Finally, financial assistance programs such as the Federal Small Business Innovation Research Grant program are very important to young biotechnology companies and need continued support and funding.

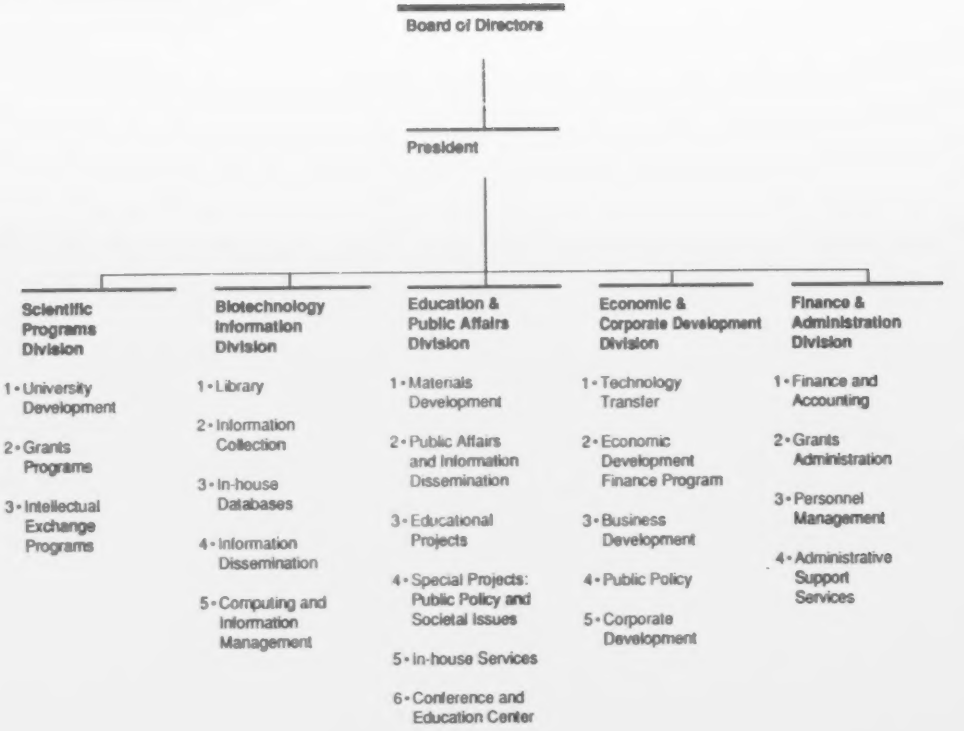
In summary, biotechnology is a new and rapidly growing technology that will have a large impact on the public's well-being. Federal efforts to enhance this industry should include:

1. assisting biotechnology centers to build business infrastructure
2. providing research funds to universities
3. enhancing the patenting process for new inventions
4. providing clear, consistent regulatory guidelines for product development
5. providing "seed funds" and various business incentives to aid the critical early development phase of "start-up" companies.

Thank you for the opportunity to present possible ways to enhance biotechnology transfer and our national competitiveness.

North Carolina Biotechnology Center

Organizational Structure and Task Areas


Board of Directors
President
Scientific Programs Division
1 • University Development
2 • Grants Programs
3 • Intellectual Exchange Programs
Biotechnology Information Division
1 • Library
2 • Information Collection
3 • In-house Databases
4 • Information Dissemination
5 • Computing and Information Management
Education & Public Affairs Division
1 • Materials Development
2 • Public Affairs and Information Dissemination
3 • Educational Projects
4 • Special Projects: Public Policy and Societal Issues
5 • In-house Services
6 • Conference and Education Center
Economic & Corporate Development Division
1 • Technology Transfer
2 • Economic Development Finance Program
3 • Business Development
4 • Public Policy
5 • Corporate Development
Finance & Administration Division
1 • Finance and Accounting
2 • Grants Administration
3 • Personnel Management
4 • Administrative Support Services

Biotechnology Information Division Attachment 2

Federal Assistance and National Activities

Federal assistance over the past year

1. Working with the International Trade Commission on a Senate Finance Committee Project on competitiveness.

2. Working with the National Research Council on a working group on U.S./Japan Technology Transfer in Biotechnology.

3. Supplied the National Agricultural Library with their biotechnology-related areas for the AGRICOLA database.

4. Provided monthly updates in data and columns for the national agricultural biotechnology bulletin board run by USDA.

5. Provided Treasury Secretary Nicholas Brady's office with figures on the small U.S. biotech companies.

6. Compiled data on all U.S. academic researchers in biotechnology with the assistance of NIH, USDA and NSF, as well as 7 key professional societies. A database and directory of this information will be available over the next half year, and will be provided to the offices at NIH, USDA and NSF that assisted in this project.

7. Provided data for the current OTA study on international competition in biotechnology. Assisted in editing this report.

8. Supplied numerous federal agencies with information from our databases, including the NIH office of technology transfer, USDA, National Research Council, and the President's Council on Competitiveness.

National Work in Biotechnology over the past year

1. Compiled the information on all U.S. biotechnology centers and made available data and wrote directory on this subject.

2. Compiled the information on all states' contact people and regulations in biotechnology and wrote directory on this subject.

3. Provided information services to by universities, companies, state governments and individuals across the United States.

4. Published a dozen articles, books and directories containing information and studies on commercial biotechnology.

5. Ongoing collaborative research with Harvard Business School, Cornell Business School, The Wharton School, UNC-Chapel Hill School of Business and Duke University's Fuqua School of Business.

Attachment 3

NORTH CAROLINA BIOTECHNOLOGY CENTER ASSISTED
TECHNOLOGY TRANSFERS FROM UNIVERSITIES TO SMALL COMPANIES

TECHNOLOGY TRANSFERRED	AFFILIATED UNIVERSITY FOR TECHNOLOGY TRANSFER/ LICENSING AGREEMENTS	COMPANY
Developed improved Rhizobium strains for peanut innoculants	NCSU	American Agricultural Services, Inc
Enhanced finfish cultivation via improved feeds	Duke	Biosponge Aquaculture Products Co
Synthesis of boronated nucleosides as therapeutic hypolipidemic and anti-inflammatory agents	Duke	Boron Biologicals, Inc
Implementation of an ultrasensitive ELISA technique to quantify blood clotting factors	Wake Forest	Elcatech
Mechanism to deliver various biologicals to poultry in-ovo; Development of growth and metabolic regulators to poultry	NCSU	Embrex
Developed a rapid, on-site assay for environmental pollutants	University of Minnesota via NC Scientists	Enaya, Inc
A rapid solid-phase test for sexually-transmitted diseases	UNC-Chapel Hill	Environmental Diagnostics, Inc
Immobilization of enzymes on carrageenan and colloidal gold particles for application in organic synthesis and as biosensors	Duke	Enzyme Technology Research Group, Inc
Development of chair-side diagnostics for dental diseases	UNC-Chapel Hill	Forte Diagnostics
An automated gene detection instrument to rapidly process samples employing Cetus' polymerase chain reaction technology	UNC-Chapel Hill	Gene-tect
Gene modification technology utilizing viral insertion vectors for improvements in poultry production and health	NCSU	Gentra Systems, Inc
A physiological test for stress resistance in maize	NCSU	Maize Genetic Resources
Identification techniques for pathogenic organisms in production of poultry vaccines for respiratory diseases	NCSU	Pathogene Biologics, Inc
Development of a DNA synthesis retarding antibiotic	NCSU	Probiologics International, Inc
Identifying lipid moieties in vascular circulation responsible for atherosclerosis and arteriosclerosis	Duke	Sphinx Biotechnologies Co
Development of a diagnostic test for opthamologic diseases	UNC-Chapel Hill & Duke	Touch Scientific, Inc

Mr. VALENTINE. Thank you, Dr. Hamner.

Mr. Marcuson.

Mr. MARCUSON. Thank you, Mr. Chairman.

It is a pleasure for me to be here today and provide my thoughts on the issue of technology transfer and mechanisms which we at Embrex have very aggressively used to obtain such technology.

Embrex is an agricultural biotechnology company using new technologies to answer the needs of the poultry industry, incidentally, North Carolina's number one agricultural product. Targeted areas for our products are the improvement or replacement of traditional chemicals, biologicals and husbandry practices to improve animal health, welfare, productivity and efficiency of labor. These products will be delivered in-ovo, that is, to the egg, using a proprietary automated injection system which we have developed based on a patented process discovered in 1984 by Dr. Jagdev Sharma, at that time with the USDA's Agricultural Research Service's East Lansing, Michigan regional Poultry Research Laboratory. He demonstrated that antigens delivered in-ovo provided effective immunity for the life of the bird.

Thus, the core technology for our company was licensed in June 1986, exclusively from the USDA. Everything we have done since was either based on or developed from that technology, the technique of in ovo vaccination. This technology was the first ever licensed under the Technology Transfer Act of 1986. This Act, as you know, was designed to facilitate the transfer of technology developed in government laboratories to private industry.

Our relationship with the USDA continues. In 1987, Embrex entered into another agreement with the USDA to collaborate on the development of a coccidiosis vaccine for poultry which might also be delivered in-ovo.

Further, in 1988, we licensed exclusively, again from the USDA, technology relating to avian interleukin-2, which, because it improves vaccine performance and enhances the effectiveness of our core technology, provides a healthier, better performing bird. This also was done under the Technology Transfer Act of 1986 via the Department of Commerce.

Additionally, the USDA has provided via the Small Business Innovation Research Program, a number of grants, the largest one for $230,000 for work in which we demonstrated for the first time that we can effectively administer substances to poultry embryos on a commercial scale via an automated injection machine.

As you can see, not only does our foundation rest on core technology obtained from the USDA, there is a very strong synergistic effect between that technology and additional technology provided by the USDA and further developed with us.

Our collaboration with universities is also extensive. At North Carolina State University, we have provided some $70,000 in direct research funding to various departments at NCSU and have, in conjunction with the North Carolina Biotech Center, provided in excess of $100,000 for improvements in poultry grow-out facilities at N.C. State in conjunction with collaborative research efforts. We provide annual scholarships to the Department of Poultry Science, the Veterinary Medical Foundation and the Agricultural Foundation in the amount of $1000.

Further, N.C. State owns 25,000 shares of Embrex stock supporting graduate studies in poultry physiology and molecular genetics and avian medicine.

As you can see, the relationship with N.C. State is extensive and fundamental to our success. But we also actively work with Mississippi State in the area of poultry grow-out and have obtained from the University of Arkansas rights to a very exciting product.

The support we have received for our effort does not stop at universities. The resources provided by the North Carolina Biotech Center has also been critical to the development of this technology. Financially, their assistance has been substantial, well in excess of $200,000 since 1986. In addition to this funding from NCBC, the resource they provide as a source of information is invaluable. The library, journals and data base access they have certainly is beyond our capability as a small company to acquire and maintain.

As you can see, we have been very aggressive and very successful during our short five year life in accessing technology from both university and government sectors.

Success does not, however, occur just by accessing technology. That is only the first part of the equation. It must be developed to meet customer needs and problems, and this takes money.

The United States is unique in that we have entrepreneurs and institutions that are willing to risk investing venture capital in ideas, processes and concepts long before commercial utility and acceptance is demonstrated. In fact, four of our current venture capitalists are European and have complained loudly about the lack of early stage investment opportunities in Europe, and they find that their funds, while sourced in Europe, are substantially invested in the United States and Canada.

There is, however, a long, deep financial chasm to leap between concept development and commercialization and the resulting revenue generation. In fact, in addition to the full time operational job of looking after a company, the other main business of small, late stage companies such as Embrex is struggling to find money to fund activities necessary to reach break-even and profitability. There are three principal ways to do that: additional venture capital financing, which is expensive; strategic relationships with companies with interests and/or activities in the same or related areas, and this can be constraining; or going to the public market, which is fraught with its own unique set of challenges. The biotech industry today has many examples of companies with good, solid technology which have failed to make this transition or are undergoing major restructuring in the continuing struggle to transit this gap.

The reasons for the struggle are many and are often beyond the control of the company. A recession, a war, as has been talked about before, a disappointingly long time to move a product through the regulatory approval process, adverse tax policy reducing the potential return for the investor on the risk and many other factors can all impact the ability of a company to obtain additional capital.

It is in this area, however, that an interesting contrast develops between the United States and some countries in Europe. While in France week before last exploring the possibility of establishing an Embrex-Europe, I was introduced to both potential investors and

potential strategic partners via agencies which are either funded in large part by the government or are in fact part of the government. The charter of these agencies is to actively solicit developed but perhaps not yet fully commercialized technology sourced from both inside and outside France, and foster and support, in France, further research and development collaborations and commercial arrangements. These agencies aggressively provide market assessment, funding, cost subsidies, tax relief and other incentives to make it attractive for the French partner firm to pursue these kinds of high-risk arrangements.

Would this kind of very direct government involvement to help ensure final commercial success work in the United States? Perhaps not, but I feel that it is very important in this country to aggressively provide industry and the investment community the kind of incentive which places us on an equal footing with other countries. Approaches should include continued strong funding for the SBIR program, permanent research and development tax credits, capital gains tax relief and perhaps other mechanisms which would allow for a small business to assess potential markets and opportunities. I believe the technology that is discovered and developed in this country by the government, universities, and companies, whether large or small, should be given the strongest possible chance to be commercialized in the United States. We should be the first to reap the benefits of our system and its incredibly strong, innovative and entrepreneurial capability.

Thank you.

[The prepared statement of Mr. Marcuson follows:]

FIELD HEARING ON BIOTECHNOLOGY
AND TECHNOLOGY TRANSFER

May 6, 1991
Randall L. Marcuson
Embrex, Inc.

It is a pleasure for me to be here today and provide my thoughts on the issue of technology transfer and mechanisms which we at EMBREX have used to obtain such technology.

EMBREX is an agricultural biotech company using new technologies to answer the needs of the poultry industry - incidentally, North Carolina's number one agricultural product. Targeted areas for our products are the improvement or replacement of traditional chemicals, biologicals and husbandry practices currently used, to improve animal health, welfare, productivity and efficiency of labor. It is our aim at EMBREX to develop and commercialize products which prevent disease, maintain health and improve productivity in terms of improved feed utilization, shorten time to market, develop more meat tissue, and so on. These products will be delivered in ovo - that is, to the egg - using a proprietary automated injection system which we have developed based on a patented process discovered in 1984 by Dr. Jagdev Sharma, at that time with the USDA's Agricultural Research Service's East Lansing, Michigan, Regional Poultry Research Laboratory. He demonstrated that antigens delivered in ovo provided effective immunity for the life of the bird.

Thus, the core technology for our company was licensed in June 1986, exclusively, from the United States Department of Agriculture. Everything we have done since is either based on or developed from that technology - the technique of in ovo vaccination. This technology was the first ever licensed under the Technology Transfer Act of 1986. This act, as you know, was designed to facilitate the transfer of technology developed in government laboratories to private industry.

In 1987 EMBREX entered into another agreement with the USDA to collaborate with Dr. Michael Ruff of the USDA's Agricultural Research Service at Beltsville, Maryland, to develop a coccidiosis vaccine for poultry which might also be delivered in ovo. Such a product would address a market which today has a value in excess of $300M. We have the option to negotiate exclusive rights to any patentable inventions which might come out of this effort. So far, EMBREX has invested $40,000 in this effort.

Further, in 1988 we licensed exclusively, also from the USDA, technology relating to Interleukin-2 which, because it improves vaccine performance and enhances the effectiveness of our core technology, provides a healthier, better performing bird. This also was done under the Technology Transfer Act of 1986 via the Department of Commerce.

Just a year ago we started working with Drs. Cox and Bailey of USDA's Richard B. Russell ARS Center in Athens, Georgia, through the in ovo delivery technique, on ways to effectively prevent salmonella from colonizing the embryonic gut which, if successful, could have a major impact on reducing this problem.

Additionally, the USDA has provided via Small Business Innovation Research Grants, $230,000 for work in which we demonstrated for the first time that we can effectively administer substances to poultry embryos on a commercial scale via an automated INOVOJECT injection machine. We have also received a grant for $50,000 for the development of a live/dead embryo detection device which, in conjunction with the INOVOJECT injection machine, will eliminate non-fertilized and/or diseased eggs from being placed in the hatchery, ensuring that only viable eggs are transferred to the hatchery. This will reduce contamination and disease transmission to newly hatched chicks.

As you can see, not only does EMBREX's foundation rest on core technology obtained from the USDA, there is a very strong synergistic effect between that technology and additional technology provided by the USDA and further developed by us.

Our collaboration with universities is also extensive. You might be interested in some statistics showing how closely involved we are with North Carolina State University. We have five active NC State academicians working with us as consultants in poultry science, engineering and food science. We currently employ a total of 32 persons - 11 of whom are either graduates of, or were scientists at, NC State. Presently two of our employees are pursuing further academic work at NC State. Three of our employees are adjunct professors in the Poultry Science Department. We have provided some $70,000 in direct research funding to various departments at NCSU and have provided in excess of $100,000 for improvements in grow-out facilities at NCSU in conjunction with collaborative research efforts. We provide annual scholarships to the Department of Poultry Science, the Veterinary Medical Foundation and the Agricultural Foundation in the amount of $1,000.

Further, NCSU owns 25,000 shares of EMBREX stock supporting graduate studies in poultry physiology and molecular genetics and avian medicine.

As you can see, the relationships with NC State is extensive and fundamental to our success. But we also actively work with Mississippi State in the area of poultry grow-out and have obtained from the University of Arkansas rights to a very exciting product. This product will have virus neutralizing utility for common avian diseases, enhancing the performance of many vaccines, both in ovo and post-hatch. We have funded approximately $200,000 of related research at the University of Arkansas

The support we have received for our effort doesn't stop at universities - the resources provided by the North Carolina Biotech Center have also been critical to the development of this technology. Financially, their assistance has been substantial. In 1986, NCBC and EMBREX together provided a joint grant in the amount of $125,000 -- $95,000 from NCBC and $30,000 from EMBREX to NCSU, which allowed them to fit up a poultry genetics laboratory.

Also in 1986, a grant of $33,000 was awarded to EMBREX for work on a naturally occurring peptide which eliminates broody behavior in layers and improves egg production. This is our avian invention on a compound which came to us from the Veterans Hospital at Tulane University in Louisiana.

In 1987 a grant of $138,000 was awarded allowing us to study the impact of another peptide on improving hatchability in broilers. The application of placing this peptide in ovo was developed at NC State.

Further, in 1988, $50,000 was awarded which allowed us to explore the application of gene insertion technology to poultry.

In addition to this funding from NCBC, the resource they provide as a source of information is invaluable - the library, journals and data base access they have certainly is beyond our capability as a small company to acquire and maintain.

As you can see, we have been very aggressive during our short 5 year life in accessing technology from both university and government sectors.

Success does not occur, however, just by accessing technology - that's only the first part of the equation. It must be developed to meet customer needs and problems and this takes money.

The United States is unique in that we have entrepreneurs and institutions who are willing to risk investing venture capital in ideas, processes and concepts long before commercial utility and acceptance is demonstrated. In fact, four of our current venture capitalists are European and have complained loudly about the lack of early stage investment opportunities in Europe and they find that their funds, while sourced in Europe, are substantially invested in the U.S. and Canada.

There is, however, a long, deep financial chasm to leap between concept development and commercialization and the resulting revenue generation. In fact, in addition to the full time operational job of looking after a company, the other main business of small, late stage companies such as EMBREX is finding money to fund activities necessary to reach break even and profitability. There are three ways to do that - additional venture capital financing, which is expensive; strategic relationships with companies with interests and/or activities in the same or related areas (this can be constraining); or going to the public market which is fraught with its own unique set of challenges. The biotech industry has many examples of companies with good technology which have failed to make this transition or are undergoing major restructuring in the continuing struggle to transit the gap.

The reasons for the struggle are many and often are beyond the control of the company. A recession, a war, a disappointingly long time to move through the regulatory approval process, adverse tax policy reducing the potential return for the investor on the risk, and many other factors can all impact the ability of a company to obtain additional capital.

It's in this area, however, that an interesting contrast develops between the U.S. and some countries in Europe. While in France the week before last, I was introduced to both potential investors and potential strategic partners via agencies which are either funded in large part by the government or are, in fact, part of the government. The charter of these agencies is to actively solicit developed but perhaps not yet fully commercialized technology sourced from both inside and outside France and foster and support in France further research and development collaborations and commercial arrangements. These agencies aggressively provide market assessment funding, cost subsidies, tax relief and other incentives to make it attractive for the French partner firm to pursue these kinds of higher risk arrangements.

Would this kind of very direct government involvement to help ensure final commercial success work in the United States? Perhaps not. But I feel that it's very important in this country to aggressively provide industry and the investment community the kind of incentive which places us on an equal footing with other countries. Approaches should include continued strong funding for the SBIR program, permanent research and development tax credits, capital gains tax relief and perhaps other mechanisms which would allow for small businesses to assess potential markets and opportunities. I believe that technology that is discovered and developed in this country by the government, universities and companies, whether large or small, be given the strongest possible chance to be commercialized in the United States. We should be the first to reap the benefits of our system and its incredibly strong innovative and entrepreneurial capability.

Thank you.

Randall L. Marcuson joined EMBREX on January 1, 1990, as President and Chief Executive Officer. Prior to coming to EMBREX, Mr. Marcuson was Vice-president, Animal Health Products for the International Agricultural Division of American Cyanamid Company. Mr. Marcuson joined American Cyanamid in 1984 after 10 years of domestic and international marketing experience with Monsanto Agricultural Products Company. Marcuson holds a B.A. degree in international relations from the University of Kansas.

Mr. VALENTINE. Thank you, Mr. Marcuson.

Dr. Reisner.

Dr. REISNER. Chairman Valentine, Representative Rohrabacher, it is a distinct pleasure to be able to share my views on the role of universities in technology transfer in the area of biotechnology. A particular pleasure because of the bad press university/industry technology transfer programs have run into from the industrial community of late. A recent industrial research roundtable claims—and I quote the summary—"Industry is the primary source for innovation. Universities play only a limited role in this realm." Troubling words perhaps. But on the other hand, kudos are given for the value of university/industry technology transfer in the field of biotechnology. Hubert Shoemaker, CEO of Centocor, Inc., a firm which of course is heavily engaged in biotechnology, tells us that his company is oriented "to look outward for its sources of technology" and relies "heavily on academic collaborations".

Even accepting the research roundtable view that industrial innovation is a process of small incremental improvements to products and processes, the goal of United States industrial competitiveness on the international market demands close collaborative links between the academic and industrial scientist. Seen in a synoptic sense, university/industry technology transfer should be the keystone which stabilizes the collaborative structure.

Given my background of having directed an NSF Industry University Collaborative Research Center in an area of immunotechnology, of serving as a current member of the UNC Patent Committee, and supervising a research program which has resulted in two products being brought to market, how do I see the reality of university/industry technology transfer today, and what suggestions would I make for tomorrow?

Let us start with the definition of what is common between the industrial and academic views of the role of the university. Both stress the absolute necessity of the university's traditional role in teaching. The technicians, researchers and engineers trained by our universities power technological development in United States industry. Industry and academe also agree that the role of the university researcher is to provide the basic break-throughs which enable the long pathway of industrial development. Neither university nor industry believe the role of the academician is product development. It is ironic, therefore, that the majority of technology transfer involves a product. For all the vaunted talk of intellectual property, university technology transfer offices deal in devices, reagents and occasional processes; rarely do they deal in concepts. There are a number of reasons for this: (1) Faculty report products to a technology transfer office as inventions because they are easy to recognize as such. (2) The technology transfer office understands such products. The technology transfer office feels they are easy to license and protect. Negotiations can be straightforward and based on exclusive use and royalties. (3) Difficult questions of intellectual collaboration can be avoided. Certainly product licensing arrangements can be of mutual economic benefit. I believe, however, that they do very little to further the goal of long-term economic development. Worse, such arrangements may lead to distrust and mis-

understanding between the academic researcher and industry because of inappropriate expectations on the part of both.

Technology transfer from university to industry based on licensing of a developed product or process certainly has a place. Such transfers provide society with the immediate fruit of the research that the taxpayer has financed. They may also provide the university-based scientist with funds to further research. To be successful, such activity requires expertise in the area of licensing so ably provided for us by Bill Riley and his associates at TULCO, and also knowledge of a variety of legal areas. The cost of such endeavors is unlikely to be quickly repaid by the monetary return from licensed products.

More critical to long-term technological development and United States competitiveness on the international market is the development of close one-on-one relationships between industrial and academic scientists. This can have the benefit of introducing industrial organizations to students, their future industrial scientists, during the most critical point of training. Such relationships also allow rapid access to the basic, non-targeted research that our universities do so well. Close collaboration also allows the academic research scientist access to the particular skills and goal directed viewpoint of his or her industrial peers. In my experience, exposure to this gestalt can help in the most basic research questions. And of course, there is much to be said for encouraging academic researchers to consider the potential societal benefit of their work.

How can we encourage these cross cultural interchanges between the academic and corporate scientist? Industry and university appear to speak the same language. But each uses a grossly different dialect in which common words and phrases have subtle but important differences. We need organizations that come staffed with linguists and anthropologists who can help bridge the cultural gaps. The North Carolina Biotechnology Center serves as a model for such an organization. Its staff understands both the academic researcher and industrial scientist and is in part derived from both. The NCBC can speak both the language of startup, middling and major industry and translate to scientists in all the research based universities in North Carolina. But its services go far beyond that. It explains biotechnology to the citizen at large and shows the high-school student how interesting and important this area is. The NCBC helps to train the undergraduate and graduate student to become the developers of tomorrow's biotechnology. I can sincerely attest to the effectiveness of the Biotechnology Center in getting the industrial and academic scientists to work together at the nuts and bolts level and thereby providing the framework for the most meaningful kind of technology transfer.

My particular suggestions to this subcommittee stress expanding support for such organizations. The NCBC has already proven its capabilities and I am certain that given modest support it can continue to expand its role in promoting technology transfer in this state and continue to serve as a model for programs at a national level.

A second way to encourage close ties between industry and university is to provide positive financial re-enforcement for joint industry/university graduate training programs. Corporate financing

of students in academic laboratories can build lasting ties between industry and university while leveraging basic research of industrial significance. With the drastic decline in NIH training grants, moderate tax incentives to industry might encourage private sector support for this critical area of training.

Another suggestion would be the provision of financial incentives to universities and industries to encourage joint purchasing of major research equipment. Industry is often short on skilled hands but long on funds for capital purchases. Universities are delighted to provide skilled hands to operate sophisticated equipment. Experience teaches that having industrial and academic scientists jointly trying to debug the latest software or get the latest piece of analytical equipment running will build close and productive collaborations.

For my last suggestion, I can do no better than to quote Representative Valentine who, speaking in Granville County, stated, "The business community should have at the top of its list bringing to bear on public officials to do something about education even if it means raising your taxes and mine". Today's public school students will develop tomorrow's technology. So I can only say amen and thank you.

[The prepared statement of Dr. Reisner follows:]

Comments To The House Subcommittee on Technology and Competitiveness
Representative Tim Valentine, Chairman.

Presented by Howard M. Reisner

Representative Valentine, Members of the Committee, it is a distinct pleasure to be able to share my views on the role of universities in technology transfer in the area of biotechnology. A particular pleasure because of the "bad press" university industry technology transfer programs have run into from the industrial community of late. A recent Industrial Research Roundtable entitled "Industrial Perspectives on Innovation and Interactions with Universities[1]" claims (and I quote the summary) "Industry is the primary source for innovation. Universities play only a limited role in this realm." Troubling words perhaps. On the other hand kudos are given for the value of university industry technology transfer in the field of biotechnology. Hubert Schoemaker CEO of Centocor Inc. a firm heavily engaged in biotechnology, tells us that his company is oriented "to look outward for its sources of technology" and relies "heavily on academic collaborations.". This favorable attitude is undoubtedly due to the fact that biotechnology has grown from the university laboratory to the start up company and even to major pharmaceutical, agricultural and chemical industries with stunning rapidity. Many Corporate officers of startups are likely to remember their recent university tenures. Although changes in the nature of technology transfer between a maturing biotechnology industry and universities are both inevitable and healthy, I am committed to maximizing such interactions. Even accepting the Research Roundtable view that industrial innovation is a process of small incremental improvements to products and process, the goal of US industrial competitiveness on the international market demands close collaborative links between the academic and industrial scientist. Seen in a synoptic sense, university/industry technology transfer should be the keystone which stabilizes the collaborative structure.

Given my background of having directed an NSF Industry University Collaborative Research Center in immunotechnology, of serving as a member of the UNC Patent Committee, and supervising a research program which has resulted in two products brought to market, how do I see the reality of university industry technology transfer today and what suggestions would I make for tomorrow? Let us

start with the definition of what is common between the industrial and academic view of the role of the university. Both stress the absolute necessity of the university's traditional role in teaching. The technicians, researchers and engineers trained by our universities power technological development in US industry. Industry and academe also agree that the role of the university researcher is to provide the basic breakthroughs which enable the long pathway of industrial development. Neither university nor industry believes the role of the academician is product development. It is ironic therefore, that the majority of technology transfer involves a product. For all the vaunted talk of intellectual property, university technology transfer offices deal in devices, reagents and occasional processes; rarely do they deal in concepts. There are a number of reasons for this. (1) Faculty report products to a technology transfer office as inventions because they are easy to recognize as such. (2) The technology transfer office understands such products. The technology transfer office feels they are easy to license and protect. Negotiation can be straightforward and based on exclusive use and royalties. (3) Difficult questions of intellectual collaboration can be avoided. Certainly product licensing arrangements can be of mutual economic benefit. I believe however that they do very little to further the goal of long term economic development. Worse, such arrangements may lead to distrust and misunderstanding between the academic researcher and industry because of inappropriate expectations on each side.

Technology transfer from university to industry based on licensing of a developed product or process certainly has a place. Such transfers provide society with the immediate fruit of the research that the taxpayer has financed. They may also provide the university based scientist with funds to further research. To be successful such activity requires expertise in the area of licensing so ably provided to us by Bill Riley and his associates at TULCO and also knowledge of a variety of legal areas. The cost of such endeavors is unlikely to be quickly repaid by the monetary return from licensed product.

More critical to long term technological development and U.S. competitiveness on the international market is the development of close one-on-one relationships between industrial and academic scientists. This can have the benefit of introducing industrial organizations to students, their future industrial scientists, during the most critical point of training. Such relationships also allow rapid access to the basic, non-targeted, research that our universities do so well. Close collaboration also

allows the academic research scientist access to the particular skills and goal directed viewpoint of his or her industrial peers. In my experience, exposure to this gestalt can help in the most basic research questions. And, of course, there is much to be said for encouraging academic researchers to consider the potential societal benefit of their work.

How can we encourage these cross cultural interchanges between the academic and corporate scientist? Industry and university appear to speak the same language, but each uses a grossly different dialect in which common words and phrases have subtle but important differences. We need organizations that come staffed with linguists and anthropologists who can help to bridge the cultural gaps. The North Carolina Biotechnology Center serves as a model for such an organization. Its staff understands both the academic researcher and industrial scientist and is in part derived from both. The NCBC can speak the language of start-up, middling and major industry and translate to scientists in all the research based universities in North Carolina. But its services go far beyond that. It explains biotechnology to the citizen at large and shows the high-school student how interesting and important this area is. The NCBC helps to train the undergraduate and graduate student to become the developers of tomorrow's biotechnology. I can sincerely attest to the effectiveness of the Biotechnology Center in getting the industrial and academic scientist to work together at the nuts and bolts level and thereby providing the framework for the most meaningful kind of technology transfer.

My particular suggestions to this subcommittee stress expanding support for such organizations. The NCBC has already proven its capabilities and I am certain that, given modest support, it can continue to expand its role in promoting technology transfer in this State and serve as a model for programs at a National level. A second way to encourage close ties between industry and university is to provide positive financial reenforcement for joint industry university graduate training programs. Corporate financing of students in academic laboratories can build lasting ties between industry and university while leveraging basic research of industrial significance. With the drastic decline in NIH training grants, moderate tax incentives to industry might encourage private sector support for this critical area of training. Another suggestion would be the provision of financial incentives to universities and industries to encourage joint purchasing of major research equipment. Industry is often short on skilled

hands but long on funds for capital purchases. Universities are delighted to provide skilled hands to operate sophisticated equipment. Experience teaches that having industrial and academic scientists jointly trying to debug the latest software or get the latest piece of analytical equipment running will build close and productive collaborations. For my last suggestion I can do no better than to quote Representative Valentine who speaking in Granville County[2] stated "The business community should have at the top of its list bringing to bear on public officials to do something about education even if it means raising your taxes and mine" Today's public school students will develop tomorrow's technology so I can only say Amen. Thank You.

Citations

[1] **Industrial Perspectives on Innovation and Interactions with Universities** National Academy Press, Washington D.C. 1991. Several unattributed or unsourced quotations also come from this publication. It should be required (albeit unsettling) reading for anyone interested in university industrial relations. The interested reader should also refer to an editorial in Science (**Industrial Interactions with Universities** P. H. Abelson Science 252:9 1991.) which refers to the above.

[2]**School Support Stressed** bylined William Woltz, Durham Herald-Sun Sunday 28 April 1991

Mr. VALENTINE. Thank you, sir.

Dr. Lehmann.

Dr. LEHMANN. Chairman, Congressman. Before I begin, I want to add thanks to you two for joining us here. I know that your agendas are full and there were probably ten other things that you could have been doing. But given the priorities of the day, we were pleased that you would talk to us and visit with us a little bit about technology transfer and for Dr. Sigmon for setting it up and his good efforts in that are appreciated.

A little bit about Ciba-Geigy before I begin. Ciba-Geigy is an international company based in Switzerland, United States headquarters in Ardsley, Agricultural headquarters in Greensboro, North Carolina. Our biotech center is here in Research Triangle Park. We are in the pharmaceutical business, agricultural chemical business, other chemicals as well as high-performance composite materials.

In agriculture, we are keenly interested in agricultural chemicals; the seeds business—corn seed, sorghum seed, alfafa seed, soybean seeds; as well as animal health products. Specifically in biotechnology our focus has been and will continue to be for awhile, the development of recombinant biologicals for plant protection, recombinant work in plants so plants can defend themselves against disease and insects as well as high technology breeding tools for the plant breeders of the future.

My responsibilities specifically, and have been for the last month and a half, have dealt with the biotech elements, the agricultural biotech elements of the business here in this area. They focus on public affairs and regulatory affairs, contracts and licensing intellectual property as well as the administrative functions.

Ciba-Geigy, in general, believes and has thought these thoughts for some time since the initial investment years ago, that plant biotechnology and agricultural biotechnology is going to be a key contributor to American agriculture in the 21st century. And we look at that from several elements, not only from today's safe food supply that we have in this country, abundantly and reasonably priced, but also for a lever of the technologies into the future, so that United States farmers can maintain their competitive advantage and continue the export success that they have.

Now one thing different about the agricultural biotechnology that I will speak to, basically dealing with the plants and plant protection microbes that, unlike our pharmaceutical friends who have already opened their box of biotechnology and dug into it and found products and millions of dollars in sales, we in the agricultural area have just found the key and opened our box. Now we know it is deep, we know it is wide, we know it is rich, but we are just at the beginning. And a lot of what I will discuss will be on that process and whether it is technological innovation as Foster speaks about it in one of his books where you go for a long period of time with research and development efforts and then finally find the breakthroughs and all of a sudden the stresses and strains begin because you have a structural change. I will speak to some of those structural changes.

First of all though, the United States competitiveness. In 1982, Ciba-Geigy made a decision to site its world headquarters of agri-

cultural biotechnology research here in the states. Now that was an important decision and we made it for several reasons strategically at that time. One is we thought the technology would be developing here. And two, we thought the political climate would be developing here so that we could foster and nurture the technology. And on both counts, I am happy to say that I think we were correct and the President's Report on Competitiveness that related to biotechnology policy just cited that, the United States is a world leader in agricultural biotechnology right now. I think the field test data that we see also speaks to that. And where we have had 180 or so field tests in the world, almost half of those have been in the United States for recombitant DNA products—half in the United States. Our next closest competitor on that list being France, would be half of our own size. I would mention also the Japanese are keenly interested in this too.

So from the field test standpoint, it has developed here since 1986. And if you look at the number of crops that have been transformed in field tests—just the number of tests—both of the graphics demonstration of the progress.

Now that is at the same time while some of our European countries are still grappling with the regulatory framework of how to test these recombitant products. And I can speak specifically to that. In Switzerland just last week where the government was going to conduct its first recombitant field test, Greenpeace occupied the field for virus-resistant potato. So we think we have made good progress and we are proud of it.

I would like to speak to several elements for the next couple of minutes here, about this process of going from the small scale field tests that we have had—

Mr. VALENTINE. The whole field? Did they occupy the whole field?

Dr. LEHMANN. No, not a whole field, usually ten acres or less, and very small, but going to large-scale tests. And also the commercialization process, Congressman.

A couple of elements of that. One is thinking to the 21st century first of all, and what we need to help you have your health, is support for basic research—basic research. The kind that brought us the lasers and transistors, the kind that brought us—that will bring us the recombitant DNA technologies for the next century, is continued and needs to be funded. I think there are strains on that because there are many good projects going unfunded, there is infrastructure already in place where government can help and contribute to consortiums and conferences to have the interchange. So basic research is one element of concern that continues to need to be funded in spite of the constraints that you will find in the budget that we get to read about daily.

Number two is intellectual property protection. We are investing in this technology, we have been investing in this technology for over a decade. We do not have a product today. Some day soon we hope to have a product, but intellectual property protection is key to getting a return on that investment—it is key.

We can look at it from a couple of different elements, one that I would speak to right now is the Patent and Trademark Office, their backlog. Dr. Hamner cited it, we are concerned too. Because

of that backlog, the proposed solution of adding examiners, 270 over the next five years, may not keep up with the influx because with laboratories and scientists continuing to work and making little steps and inventions, there are going to be more and more patents and the backlog may get larger as we go through time because of that invention. And I can speak specifically to patent applications that we are aware of that took place in early 1983 that have not issued. I have been in the meetings where we try to focus our research and decide on paths, but we are saying, gee, if we get blocked here, maybe we should be working on this area but we do not know because the issue has not patented, we do not know if we need to be talking to somebody else or ourselves. From 1983 to now is a long time and we hope that that will get resolved soon. I know the average is only two years, but averages can kill you when they are instrumental patents on both of that. So that is a long time ago. So the intellectual property protection is key.

The final area that I would speak to briefly is getting to the commercialization process, how to get out of small scale field tests and into the watchful eye of the United States Department of Agriculture which whom we have enjoyed the cooperation of the EPA, we fostered that and we have progressed that way, but now we are at a stage of how do we get commercial. There are a couple of elements that we need to get commercial with too because this lead that we have in plant biotechnology today and agricultural biotechnology will not stay. You know, others will find a way, but we think to stay we have got to find the commercialization process.

Now I have brought with me today and I have attached to my written comments, a white paper authored by the Association of Biotechnology Companies and the Industrial Biotechnology Association, two trade associations that Ciba-Geigy is a member of that represent biotechnology that speaks in more details to the needs; you know, the regulatory and intellectual property more eloquently than maybe I have in the last few minutes. But that paper is attached to my comments if anyone wants to see it.

But I would just like to note a few and I will just note them quickly. In general, the Administration and Congress should oppose any new regulatory structures or modifications of existing regulatory structures through new legislation. And the reason we say that is we have got a great infrastructure with the USDA and with the EPA and with the FDA that having new structures will not, we do not think complement that. And these agencies have got a rich history over the field test applications and gotten that over the last several years.

I think in addition to that, number two, is that we need to have the federal agency acknowledge the growing body of field test data that supports the safety of the transgenic crops. And with that safety demonstrated, work on fast track approval systems for those that have been proven safe—faster than we might find otherwise through regulatory review.

Now specifically I could speak to a couple that we think the EPA should promptly issue regulatory regulations for experimental use permits for microbial pesticides, recombitant ones, and regulatory policies for pesticidal transgenic plants. Because with those, we believe that we can have 10 to 20 new products on the market within

the next few years that would lead to those two areas, but the regulatory framework is still developing.

We also believe that as the federal government develops the regulatory framework and puts it in place, that that will limit other entities, states or otherwise, in developing what may be burdensome regulatory—duplicate efforts.

Finally, we would encourage Congress and the Administration to act to address the biotechnology backlog in the Patent and Trademark Office. The Boucher Biotechnology Patent Protection Act that would ensure the potential for processes, some processes in biotechnology, to be patented, would be of help.

And then finally, as I began, the funding of basic research that will get us into the next—continue the competitiveness and get us into the next century.

I thank you too.

[The prepared statement of Dr. Lehmann follows:]

Statement to the

CONGRESSIONAL SUBCOMMITTEE ON TECHNOLOGY AND COMPETITIVENESS

by Dr. J. Dan Lehmann
CIBA-GEIGY Corporation

May 6, 1991

Addendum

AGRICULTURAL BIOTECHNOLOGY: REGULATORY AND POLICY ISSUES

Joint Position Paper of the Industrial Biotechnology Association
and Association of Biotechnology Companies

Statement to the

CONGRESSIONAL SUBCOMMITTEE ON TECHNOLOGY AND COMPETITIVENESS

by Dr. J. Dan Lehmann
CIBA-GEIGY Corporation

May 6, 1991

INTRODUCTION

On behalf of CIBA-GEIGY Corporation and the CIBA-GEIGY Seed and Agricultural Divisions, I thank you for this opportunity to express our thoughts and concerns regarding the issues of technology transfer and global scientific competitiveness as they relate to agricultural biotechnology.

I am Director of Development, Planning and Administration for CIBA-GEIGY's Agricultural Biotechnology Research Unit here in Research Triangle Park, North Carolina. My current responsibilities include Regulatory and Public Affairs, Contracts, Licensing and Patents as well as overall facility planning and administration functions.

CIBA-GEIGY is a Swiss-based company with interests in agriculture, pharmaceuticals, chemicals, and composite materials. Our U.S. agricultural headquarters are located in Greensboro, North Carolina. The Agricultural Division develops and markets 1) plant protection chemicals and biologicals, 2) improved corn, sorghum, soybean, and alfalfa seeds, and 3) animal health products.

We are strongly committed to the use of technological innovation for the development of new products that will provide benefits to farmers and consumers well into the 21st century. Toward this end, we have an active program in agricultural biotechnology research, right here in Research Triangle Park, approximately two miles from where we are gathered today. At this facility, we are engaged in research aimed at producing effective and environmentally compatible biological pesticides, and crops genetically enhanced through recombinant DNA techniques to 1) resist attack by pathogens and insects and 2) advance plant breeding technologies.

We believe that agricultural biotechnology will, starting in the mid to late 1990's, prove to be a key component in managing crop production and maintaining the safe, abundant, and relatively inexpensive food supply which U.S. consumers are privileged to enjoy. In addition, the technology will be the "lever" that will enable the U.S. to maintain the competitive advantage we have in agricultural production to support, not only our own standard of living, but also U.S. farm exports.

U.S. COMPETITIVENESS IN AGRICULTURAL BIOTECHNOLOGY

In 1982, CIBA-GEIGY made an important strategic decision to place its agricultural biotechnology research facility in the U.S. It was widely perceived at the time that the technical expertise and political climate required to reach the desired goals lie here in the U.S. This decision has

proven to be a good one: The U.S. has become the world leader in agricultural biotechnology research. CIBA-GEIGY's decision was substantiated by the conclusions reached in the recent Report on National Biotechnology Policy by the President's Council on Competitiveness.

The record of field tests of transgenic crops bears this out. Through the end of 1990, approximately 180 field tests of engineered crops had been conducted in 12 countries. The U.S. accounted for the majority of these with 44 percent, with France, Belgium and the United Kingdom trailing with 22, 14, and 7 percent, respectively. By the end of this summer, approximately 150 field tests of engineered crops will have been conducted by academic, government, and industry researchers in the U.S. This has occurred under the careful oversight of the USDA's Department of Biotechnology, Biologics and Environmental Protection, often in consultation with the U.S. Environmental Protection Agency.

If, as we believe, field tests are the stepping stones to commercial development and release, several important food and fiber crops are nearing the point of commercialization in the U.S., while other countries with reasonably advanced research programs, such as Germany, Japan, and Switzerland, are still struggling with developing legislative and regulatory frameworks within which to test and develop the technology.

It is also noteworthy that the U.S. farmer and public are, thus far, more open to the idea of transgenic crops. Contrast the progress of public acceptance in the U.S. of these 150 field experiments to the first such experiment attempted in Switzerland last week. There, the environmental advocacy organization, Greenpeace, occupied a Swiss government research field where engineered virus-resistant potatoes were to be planted.

CRITICAL NEEDS - WHAT GOVERNMENT SHOULD DO

Funding Basic Research

Basic research has traditionally been the foundation of American scientific and technical advances and product development. Given current Federal budget constraints, it is no surprise that funding for basic research in the sciences is limited. Faced with a shortfall in Federal support, many academic researchers are increasingly turning to industry for research funding, and focusing more on applied research. Basic research - the kind that will give us the transistors, the lasers, the recombinant DNA technology of the future - is underfunded.

We think that the Federal government should dedicate more financial resources to fund basic, non-applied research in the plant, microbial and ecological sciences. The results of this research will establish the foundation for new agricultural products in the 21st century.

In addition to the need for funding basic research, we need to enhance the transfer of that knowledge base to the private sector for commercialization. We believe the rapid pace of development in the U.S. thus far is due in part to the reasonably open exchange of information and technology among academic, government, and industrial research laboratories. Support of scientific conferences by Federal agencies is very important in the technology transfer process.

Intellectual Property Protection

Significant investment is being made, and has been made since the 1970's, in biotechnology; the investors expect to earn returns based upon product introduction. As a result, the protection of intellectual property is essential for both the products and processes used to advance the science. We support the intent of the Boucher Bill, i.e., the extension of process patentability.

In addition, much could be accomplished to expedite the transfer of technologies by addressing the biotechnology backlog that currently exists at the U.S. Patent and Trademark Office (PTO). The President's Council On Competitiveness noted this backlog in their Report On National Biotechnology Policy. The addition of 270 examiners over the next five years, the proposed solution, may not be sufficiently rapid to improve the situation.

We are aware, for example, of several key patent applications filed in early 1983 that have not yet issued. It is extremely difficult to make product development decisions before the full cost and relative competitive patent positions become known.

Commercialization - "Getting Products To Market"

Another aspect of technology transfer which concerns CIBA-GEIGY is how innovative research, be it conducted by the USDA, a university or a company, will move from the stage of early, small-scale research to its full potential in the marketplace. This is the ultimate goal of any technology transfer program: the application of technology to development of products that will ultimately benefit society. The speed and effectiveness of this development of research technology into products will determine whether the U.S. will maintain its position at the forefront of biotechnology.

Given the apparent U.S. lead in agricultural biotechnology, why our concerns? For the U.S. to retain its competitive edge in the field it is vital that there be a streamlined process between research and commercialization.

While research has been proceeding, in large part due to the excellent work of USDA's APHIS Biotechnology group, the needed regulatory policy-making to address commercialization issues has not kept pace with the scientific developments. There is still a lack of clarity concerning how the products will be approved for market release and which federal agencies will play the lead role for specific products.

This may lead to delay in bringing new agricultural products to market. With a clear pathway, ten to twenty new products could be available to the farmer within the next few years. The American farmer will need these products to continue to be competitive in world markets.

We would like to offer a brief summary of recommendations, all of which are made in greater depth and detail in the report by the President's Council on Competitiveness and in a white paper drafted jointly by the Association of Biotechnology Companies and the Industrial Biotechnology Association.

CIBA-GEIGY is a member company of both trade organizations. This draft document has been attached as an addendum to our written statement.

SUMMARY OF RECOMMENDATIONS

Congress, the Administration, and the regulatory agencies should ensure that regulations and guidelines are based solely on the potential risks of the final product. As has been stated by the Ecological Society of America and the National Academy of Sciences, risk assessment should focus on the final product rather than the process by which the product was derived.

The Administration and Congress should oppose any efforts to create new regulatory structures or modify existing ones through new legislation. Current legislation has been and will continue to be sufficient to regulate agricultural biotechnology research and commercialization.

The Federal agencies should acknowledge the growing body of field test data that supports the safety of transgenic crops and institute a fast track approval system for products of proven safety.

The U.S. regulatory agencies should fully coordinate both inter- and intra-agency activity to avoid unnecessary and duplicative review efforts.

The U.S. EPA should promptly issue both its regulations for experimental use permits for microbial pesticides and its regulatory policies for pesticidal transgenic plants.

Addressing the Federal regulatory issues stated above will help limit the proliferation of burdensome and duplicative state and local legislative and regulatory initiatives.

Congress and the Administration should act to address the biotechnology backlog at the Patent and Trademark Office.

Congress should support the Boucher Biotechnology Patent Protection Act to ensure that novel biotechnology processes will be protected.

Congress should remain strongly committed to the funding of basic scientific research.

In conclusion, I thank you once again for the opportunity to participate in this hearing. I hope that these comments and the associated written statement will be useful in determining how this Congressional subcommittee can address the important issues surrounding technology transfer and global competitiveness. CIBA-GEIGY stands ready to provide any additional assistance which may be required by Congress and looks forward to such opportunities.

Dr. J. Dan Lehmann

Dr. Dan Lehmann is the Director of Development, Planning and Administration for CIBA-GEIGY's Agricultural Biotechnology Research Unit in Research Triangle Park, North Carolina. Dr. Lehmann's current responsibilities include Regulatory and Public Affairs, Contracts, Licensing and Patents as well as overall facility planning and administrative functions.

Dr. Lehmann joined CIBA-GEIGY in 1986 as Controller of Funk Seeds and in 1989 was promoted to Executive Director, Business Development, CIBA-GEIGY Seed Division. In 1990 he became Director of Planning and Analysis on the corporate staff.

Dr. Lehmann is a graduate of the University of Illinois with both B.S. and M.S. degrees in Agricultural Economics and a Ph.D. in Finance.

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Addendum

AGRICULTURAL BIOTECHNOLOGY: REGULATORY AND POLICY ISSUES

Joint Position Paper of the Industrial Biotechnology Association and Association of Biotechnology Companies

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AGRICULTURAL BIOTECHNOLOGY: REGULATORY AND POLICY ISSUES

JOINT POSITION PAPER OF THE INDUSTRIAL BIOTECHNOLOGY ASSOCIATION AND ASSOCIATION OF BIOTECHNOLOGY COMPANIES

Crop agriculture for the production of food, fiber, and timber is one of the largest sectors of the U.S. economy. The USDA Economic Research Service puts the current domestic value of raw agricultural products at $71.4 billion for the most recent year. Commerce in agricultural products either at the supply (seed and other input materials such as crop protection chemicals) or the output level (raw agricultural commodities) is international in scope. The United States has been extremely successful over recent years in taking advantage of its ability to produce both input and output agricultural items at low cost. Exports of crop agricultural related products have been a net contributor to the balance of trade. Over the past year such exports totaled $4.2 billion.

The recent development of new molecular techniques of manipulating organisms offers great promise for improving agriculture. Farmers will directly benefit as input costs for controlling weeds, diseases, and insect pests are reduced. Consumers will benefit from a more nutritious and stable food supply. Recombinant DNA (rDNA) technology is being used to move segments of genetic material between organisms imparting desirable traits to the recipient organism. Plants may be engineered in this manner to improve agronomic properties. Disease and insect resistance, tolerance to applications of "soft" or environmentally compatible herbicides, improved nutritional qualities, production of healthier oils and improved flavor are all traits that may be improved through genetic engineering.

Both large and small companies engaged in biotechnology research have recognized how biotechnology may reshape certain sectors of our agricultural system. Research and development expenditures presently total over $300 million/year in the United States. The private sector research commitment continues to grow strongly. However, without assurance of timely product commercialization this investment is tenuous at best.

The ability of scientists to probe gene structure and function will profoundly affect traditional plant breeding as well. Restriction fragment length polymorphisms can be used to identify specific genetic markers associated with agronomic properties such as water use efficiency. Thus, breeding to improve drought tolerance can be accelerated. The identification of key enzymes involved in photosynthesis will provide new avenues of enhancing the growth of major food crops. Through such techniques yields can be increased and time to maturity may

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be shortened.

Similar molecular approaches are being used to improve microbial pesticides and make their properties more compatible with the needs of commercial growers. The genes that code for insect toxins can be amplified as well as moved into new host organisms. New approaches to pest control that are fully compatible with the goals of integrated pest management can be developed using biotechnology.

From the beginning of the biotechnology revolution, the consequences of moving genetic material across reproductive barriers concerned scientists. One of the principal results of this uncertainty has been that rDNA technology has been developed in a cautious atmosphere. Containment provisions, whether for laboratory or controlled small-scale field research, have been conservatively selected. These conditions have been relaxed as accumulated scientific data confirmed that recombinant organisms are not a priori any more hazardous than their non-modified counterparts.

As the commercial prospects of using these molecular techniques became apparent, the Federal government developed a coordinated framework for the regulation of biotechnology. The framework, published in 1986, set forth agency jurisdictions over biotechnology products. Regulatory policies were put into place covering pre-commercial field research using genetically engineered plants and microorganisms. By and large, this Federal oversight process has worked well and the Agencies are to be commended for the manner in which they have handled and reviewed these early-stage research projects.

When the 1986 coordinated regulatory framework was published much of the research being conducted involved model plant systems such as tobacco and petunias. Scientists were still learning how to reliably transform crop plants. The pace of science has accelerated and virtually all crop plants important to U.S. agriculture have now been transformed using rDNA technology. Unfortunately, the needed regulatory policymaking to address commercial issues has not kept pace with the scientific developments. This ultimately may lead to delays in bringing these agricultural products into commerce. With a clear pathway, 10-20 new crop products could be available to the farming community within two years. This would include crops such as cucumbers, cantaloupe, cotton, tomatoes, and oilseed rape (canola) resistant to disease and insects, as well as expressing tolerance to environmentally "soft" herbicides. The American farmer will need these products to continue to be competitive on world markets.

In addition to the regulatory and policy issues that must be addressed in getting an agricultural product from the small-scale

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research to the marketplace, the Federal government must consider whether the accumulated knowledge from over 200 field tests of genetically modified plants and microorganisms conducted worldwide is sufficient to justify more flexible requirements and a more streamlined regulatory oversight mechanism. This would allow for the focus of attention on those projects deserving greater scrutiny, and a lessor regulatory burden on small-scale field research activities, especially those involving plants and vectors which have already been the subject of regulatory review.

These regulatory and policy points are addressed in the remainder of this paper. The overwhelming majority of biotechnology-derived agricultural products will not differ markedly from their traditional counterparts. Conceptual frameworks already exist for evaluating both the environmental and food safety issues associated with these new products. One of the powers of the molecular techniques used to modify agriculturally important organisms is that the scientists know with precision the nature and effect of the modification. This markedly simplifies the regulatory paradigm.

I. Federal Support for Biotechnology

A. Adequate Resources

The Federal government must make a firm commitment to support the coordinated regulatory framework for biotechnology. There is a need for the prompt issuance of policy in those areas that have not been totally resolved (see Part III below). This will assure the public, as well as those states that have or may contemplate separate regulatory initiatives, that a thorough oversight process is in place at the Federal level. The public must understand how the regulatory process operates and be comfortable with the decisions that result.

Agencies with regulatory responsibilities must have sufficient scientific staff and resources to review submissions. Reviews must be science based. Examinations should include possible risks that may be associated with the use of the products. The review of the process must be considered as only one portion of the overall review as is the norm with safety reviews of other products evaluated by regulatory agencies. Industry's position continues to be that products of biotechnology should be subject of regulation and not the process by which the product is derived.

B. International Harmonization

There is no question that biotechnology will lower input

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costs in our agricultural system. However, the present lack of harmonization in regulatory efforts at the international level could complicate the introduction of products from this new technology.

The problem can be broken down into two parts: regulation of input materials (e.g. a new genetically modified pesticide or seed) and secondly the regulation of output goods (e.g. grain from a genetically engineered crop). Manufacturers of environmentally compatible microbial pesticides hope that their products will not be excluded from foreign markets because of regulatory barriers. If the grain from a genetically engineered corn plant is not accepted on international markets, U.S. farmers cannot afford to plant the crop.

Each of the above issues must be dealt with by U.S. representatives in a pro-active manner during international discussions. The experience that U.S. regulators have gained from the review of agricultural field tests should be shared with our trading partners abroad. Our regulatory agency personnel who participate in the international discussions should be encouraged to share information with their counterparts on the handling of environmental and food safety assessments. The industry hopes that these discussions will deflect movements that would create artificial, non-tariff trade barriers. Such barriers would have implications beyond the biotechnology industry and could have significant impact on international trade in all agricultural commodities.

II. Coordination of Regulatory Efforts

Most of the development thus far in both the biopesticides and plant genetic engineering areas is in early stage field research. However, product commercialization is close at hand. At the commercialization stage, many products of agricultural biotechnology could be subject to multiple agency jurisdiction. Industry recognizes its responsibility to seek the appropriate regulatory approvals, but also requests that the regulatory agencies coordinate both inter- and intra-agency activities to avoid unnecessary and costly duplication in review.

For those products subject to cross jurisdictions, data requirements must be carefully defined. When two agencies are reviewing data packages at the field testing stage, efforts must be taken to avoid duplicative reviews. If the agencies have not already done so, they should institute regular meetings to discuss their respective roles in the regulatory process. As an example, the decision could be made by both FDA and EPA to rely heavily on the environmental assessment made by APHIS during their review of plant pest status and their environmental review under the National Environmental Policy Act (NEPA). A smooth

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transfer of responsibility between agencies will facilitate regulatory compliance for both the agencies and the regulated community.

An unresolved question is whether specific transgenic crop plants will require specific FDA pre-market clearance. Two FDA Centers are important insofar as crop plants are concerned. The Center for Food Safety and Applied Nutrition (CFSAN) has responsibility for human foods and food additives while the Center for Veterinary Medicine (CVM) has responsibility for animal foods and food additives. Many genetically engineered crop plants designed for food use will be fed to both humans and animals. Thus, coordination between the two FDA Centers is absolutely imperative. It is appropriate that CFSAN take the lead in coordinating the regulatory process where jurisdiction is overlapping.

Developments in agricultural biotechnology are rapidly proceeding. Virtually all environmental safety concerns have been resolved with field research. Uncertainties regarding food safety concerns will be readily resolved for the vast majority of products prior to commercial release. As supporting scientific data is acquired, it will become even more evident that a flexible regulatory system is essential, to allow for a "fast-track" approval system for the majority of products, allowing agency resources to be focussed on the few products that may present a higher level of concern.

III. Need for Regulatory Policy

A. Prompt Issuance of Microbial Pesticide Experimental Use Permit Regulations

At present EPA regulates the field testing of genetically engineered microbial pesticides under an interim policy promulgated in 1984 and modified in 1986. Since the 1986 modifications the Agency has been working on revising 40 CFR Part 172. These regulations govern the issuance of experimental use permits (EUPs). Final codification of these regulations is important for industry so that any lingering uncertainties regarding the scope of oversight are removed.

Last fall, the Office of Pesticide Programs (OPP) submitted a draft proposal to the FIFRA Scientific Advisor Panel for review. Industry was optimistic that the regulatory approach would be finalized. However, it is our understanding that the proposed rule has yet to be submitted to the Office of Management and Budget (OMB) for review.

The FIFRA Scientific Advisory Panel reviewed three proposals for the definition of scope of oversight at small-scale that

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accompanied the draft. There was general consensus that the second option which focuses on "...only those microbial pesticides whose pesticidal properties have been imparted, enhanced, or modified by the introduction of genetic material that has been intentionally manipulated" (Page 28 of the draft proposal) was scientifically sound. Industry and the FIFRA Science Advisory Panel support this view.

Prompt action by the Federal government on this matter would provide a measure of regulatory relief that is scientifically justified. Under present EPA policy, all genetically modified microbial pesticides are reviewed by the Agency prior to initial small-scale field testing. Based on their review experience of the past 8 years, EPA is proposing to limit these initial reviews to only those microbial pesticides where the pesticidal activity has been markedly altered.

We emphasize that the regulations that oversee the issuance of EUPs for genetically altered microbial pesticides (40 CFR Part 172) need to be published as soon as possible in order to give the registrants appropriate guidance, to help limit the continuing proliferation of duplicative state and local regulatory reviews, and for additional regulatory relief.

B. Prompt Issuance of a Policy on Transgenic Pesticidal Plants

EPA's Office of Pesticide Programs indicated they will consider the need for rulemaking under FIFRA to clarify the regulation of those genetically engineered plants that have inserted sequences that impart pesticidal activity to the plant. Examples are plants expressing the BT toxin gene which produces a protein lethal to certain insect pests, and plants expressing a plant virus gene making the plants resistant to viral disease.

At present, EPA allows field testing of pesticides other than certain microbial pesticides under ten acres without review by the Agency. These classes of genetically engineered plants are also subject to APHIS review. At present, APHIS submits the applications they receive to EPA for a courtesy review. It is assumed by industry that APHIS will continue its review of the plant pest status of new genetic constructs and that EPA review would be triggered when the field release exceeds ten acres or an Experimental Use Permit (EUP) is otherwise required. When EPA takes over as the primary regulatory authority, the APHIS review of the plant pest status should be essentially completed. One of the key thrusts of the coordinated regulatory framework is the need to minimize duplicative regulation.

Plants are unlikely to present any unusual environmental dispersal issues. APHIS will have carried out an environmental assessment which should address the principal environmental issues of concern to EPA. Thus, EPA should not require

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additional oversight of small-scale field testing. Current EUP regulations could be relaxed in terms of the acreage threshold for pesticidal plants. This would permit medium-scale field research to proceed without unnecessary regulatory burden.

EPA is to be commended for convening two workshops designed to address the scientific issues behind the safety evaluation of transgenic pesticidal plants. Crops possessing such traits will be near term commercial products. The Agency should use the consensus from the workshops to move promptly towards the promulgation of a regulatory policy and associated data requirements. The primary emphasis should be placed on developing applicable guidelines for plants encoding proteinaceous products. The crop plants that are given pesticidal properties through genetic modification should not be treated as though they are either chemical or microbial pesticides.

EPA has shown a great degree of flexibility in the regulation of microbial pesticides. Data requirements are reduced relative to their chemical counterparts. A similar approach should be taken with respect to pesticidal plants. EPA must adopt flexibility in terms of specific toxicological testing requirements. In virtually all cases, these plants will be incapable of producing the active ingredient at hazardous levels. Since production of the active ingredient is under genetic control, it is impossible to exceed the "recommended application rate." In addition, certain approaches involving the transfer of genes coding for anti-feeding compounds or viral coat proteins to crop plants will not result in the addition of a toxic moiety to the crop. EPA must be cognizant of these types of manipulations; the scope of oversight and data requirements must be carefully defined.

Of further concern is how the pesticidal plants will be classified during the registration process at EPA. Each year seed companies and public universities release hundreds of new varieties of row crops and vegetables for sale. Many of these have enhanced pesticidal properties but are not subject to regulation. If the Agency regulates genetically engineered plants with enhanced pesticidal properties, it would not be scientifically sound or wise policy to treat each new variety containing the same insert as a separate product requiring an individual pesticide registration.

C. The Need for an FDA Policy on Whole Foods

Traditionally whole foods are not required to undergo any premarket review or approval by FDA. It is up to the person who introduces the food into commerce to insure that the food complies with all requirements of the Food, Drug, and Cosmetic

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Act. Whole foods are subject to regulation by FDA under section 402(a)(1) of the Food Drug and Cosmetic Act. Section 402(a)(1) establishes two different safety standards -- one for substances that are inherent natural constituents of the food and one for substances that are "added." Naturally occurring constituents violate section 402(a)(1) and render the food legally "adulterated" only if they make the food "ordinarily injurious to health." "Added" substances are subject to a more rigorous safety standard. They render the food legally adulterated if they "may render it injurious to health." Thus, FDA could use this provision to regulate traditionally bred crop plants but has not found it necessary to do so. The plant breeding industry has enjoyed an enviable record of safety.

At the other end of the regulatory continuum are the food additive regulations. Food additives require explicit pre-market clearance by FDA. The new molecular techniques used for crop plant modification are extensions of traditional breeding and that crops produced by these techniques should not routinely be forced to go through the food additive petition or the GRAS affirmation petition process. Such an automatic, process-based approach would erect a substantial barrier to the development of many new plant varieties with well-characterized and useful traits. It would be inconsistent with FDA's long-established approach toward the hundreds of new varieties of crop plants with new, improved traits introduced by traditional plant breeding, including varieties with traits introduced via interspecific or intergeneric crosses with wild or weedy relatives.

How then should these new crop varieties be treated from a regulatory perspective? The International Food Biotechnology Council (IFBC), a group consisting of major biotechnology and food processing companies, surveyed the laws and regulations pertaining to foods and food products. The IFBC proposes that the regulation of genetically modified food plants derived by nontraditional genetic modification be patterned directly on existing law and practice. If the purpose of the modification is to introduce as an expression product of the transferred gene a functional chemical entity that, if introduced exogenously, would be regulated as a food additive or GRAS substance, it would be regulated in the genetically modified plant as a food additive or GRAS substance. If the purpose of the genetic modification is not to introduce a functional chemical entity but to affect some agronomic or processing function, the plant would be regulated in the first instance under section 402(a)(1) of the Food, Drug and Cosmetic Act, just as whole foods are regulated today.

The IFBC also recommends that FDA consider establishing a flexible pre-market notification system for genetically-modified food plants. Under such a system, a manufacturer would have the option of submitting to FDA at some specified time prior to marketing, and in accordance with FDA guidelines, a package of

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information documenting its safety evaluation of the modified plant and why no food additive or GRAS regulation is required. This information would be available to the public in accordance with established FDA policies and procedures under the Freedom of Information Act which protect essential trade secrets but provide for disclosure of most safety information. The submission would not trigger formal FDA review and approval of the modified plant, but it would assure that the agency was informed about the product and provide an opportunity for FDA to express an objection or concerns it might have in advance of marketing. FDA would also have the option of issuing a letter stating that it is aware of the product and, on the basis of information submitted, does not object to its marketing.

The IFBC spent considerable time and effort to define the conceptual framework for the safety evaluation of biotechnology-derived food products. The project took over two years and involved top scientists from industry and academia. Rather than prescribing stringent test protocols, the IFBC report adopted a more flexible decision tree pathway for safety evaluation. It was recognized early on that all products cannot be treated alike. Generic test protocols designed to deal with a heterogeneous group of products will in the end be inflexible.

The biotechnology industry recommends that FDA develop a premarket notification system for genetically modified crop plants as proposed in the IFBC report (described above). This would provide an avenue for companies to inform FDA and the public regarding new food crops. Companies would have an alternative to the petition process to demonstrate to FDA that these crop products are not adulterated and therefore not deserving of special regulatory oversight.

D. APHIS Should Consider Reducing the Regulatory Burden on Genetically Engineered Crop Plants

APHIS, through the use of the Federal Plant Pest Act, has principal responsibility for the oversight of field testing for genetically engineered plants. The regulatory system developed by APHIS has worked well since its promulgation in 1987. Anyone wishing to field test a genetically modified plant subject to these regulations must apply to APHIS for a permit to conduct the field test. APHIS reviews the data and, if no environmental risk is posed, issues a finding that under the specific conditions of the test the plant does not pose a plant pest risk. Subsequent field trials of the same plant require further permit applications.

This regulatory system has not been overly burdensome given the stage of development of the technology and the lack of field test data. The marked increase in field research that will take

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place over the next several years will place increasing burdens on both APHIS and the regulated community. No unique environmental hazards have been identified as a result of the field research to date. Small-scale research involving genetically modified plants can be contained through prudent agronomic practices. It is therefore reasonable and timely that APHIS consider reducing the regulatory burden. The biotechnology industry believes that this is scientifically justified, given the extensive evaluations that have been made by APHIS on specific crops, vectors, and introduced traits. The case can be made for the substitution of a notification system for field experiments that do not pose an environmental risk. Thus the APHIS regulations would evolve in the same manner that the NIH Guidelines for Recombinant DNA Research have. The oversight level should be reduced in accordance with the risk of the experiment.

Mr. VALENTINE. Thank you, sir, and thank all of you.

How many of you remember reading that there was a person in the last century—I hope his name was not Valentine—who suggested in all seriousness that the Patent Office be closed, that everything that had been invented by the mind of man—his name was not Rohrabacher either—had been done. There was no need to bother with that sort of thing.

Dr. Hamner, how much money did the state appropriate at the beginning, was it 1980 or 1981, to create this facility?

Dr. HAMNER. Yes, sir, it was out of the Governor's Office of Science and Technology and I think it was about $200,000 that was appropriated in 1982 and 1983 for the Biotechnology Center. Then the Center became a private, non-profit corporation because of the early success that it had and in 1984, it was appropriated $6.3 million by the General Assembly for operation and it has stayed at about that appropriation level until this year. And this year, the appropriation is about $7.4 million.

Mr. VALENTINE. Did the state invest heavily in the building, the capital improvements?

Dr. HAMNER. Actually, we are very pleased and proud of the way the Biotechnology building has been financed. In the end—it is currently in the process of being financed, but in the end the state will provide about a third of the funds for the building, the federal government will provide about a third of the funds and private industry will provide about a third of the monies for the building. The building will cost somewhere in the neighborhood of $5.8 million.

Mr. VALENTINE. Do you have, Dr. Hamner, a model in mind for a single point of focus, for lack of a better expression, that could help us to remove the regulatory confusion which you and others have talked about, amongst United States Department of Agriculture, EPA and FDA?

Dr. HAMNER. Well of course the Biotechnology Center has tried to be a leader in that area. Any time you go into that foray, you all as successful politicians know, industry thinks you are trying to over-regulate them and public interest groups think you are the Chamber of Commerce of industry. So it is very difficult to really say what to do.

But the governmental framework that is now in place, I think can be streamlined and focused and developed to be quite satisfactory. I think Dr. Lehmann made an excellent point when he said that biotechnology is remarkably safe. In the ten years or so that tests and field tests and other things have been going on, there has not been any dangerous episodes that I know of and I do not know that anybody else knows of any because I am sure they would have been publicized.

But I do think there is frustration with the industry in that they do not have a clear set of guidelines that they know that they can set out with the federal regulatory process and know that in a certain length of time if they do certain things, they can have a product that will be approved for further development on one hand and for commercialization on the other.

So I think it just needs to work on the framework that is already in place and I think that is being done, but it is a very slow process and it has been so frustrating because for five years we went with-

out a definition of what genetically engineered organisms were. We finally got to the point we defined that. So it is a long process, it is a difficult process. It is one where angels fear to tread. But if we can define and streamline the current framework, I think it will work fine.

Mr. VALENTINE. You are unheralded heroes because what you do, most people—well, I will not say most people, but a lot of folks think of it as kind of a Pandora's box.

Dr. HAMNER. Yes, sir.

Mr. VALENTINE. I dare say that there are very few people, intelligent people, in this area would understand much about what goes on and I should think you would have a job of salesmanship with the General Assembly to explain what you do.

Dr. HAMNER. We are certainly entering a stage where knowledge is power. And certainly when you get to biotechnology, it probably is not one-tenth of one percent of the population that understands what is happening at genetically engineered, molecular biology levels. We have such a few people with so much power that there is obviously some concern and suspicion about all of that. And people will feel better about it if we can educate them. And our Center puts a tremendous effort forth to educate the public honestly, straightforwardly about the risks and benefits of genetically engineered organisms and the various mechanisms that are being developed. And we think that is a key thing.

It worries me to see a lot of money going into research and development if we produce a lot of technologies that either the public does not understand, the public distrusts for some reason or the public does not know they need. If they will not use the products, there will not be very much commercialization to result from these things. So doing research alone, sir, is not enough. We have got to, at the same time, explain to the public honestly and straighforwardly the risks and benefits of moving ahead.

As I have said many times to the legislature in Raleigh, if we told somebody the day that we made the first automobile, which was about 1892, that it was going to kill 50,000 people a year, I am quite sure that the automobile would have been strongly resisted more than it was. But we have learned over the years that the benefit of going hither and fro is very good for us and we take the chance every morning of getting in a car and going down the road, of getting hurt. And that is the way it is.

This technology in the next century will be in the same sort of thing. You certainly will probably, you know, over time have some problems. We worry all the time about biological warfare, for instance. But the benefits coming from all of this, sir, and if we can trust one another to develop them sensibly and not use them in a war, are very, very beneficial.

Mr. VALENTINE. I do not want to elevate any North Carolinian to sainthood, unless maybe me—I was around when the Research Triangle Park came into being. I do not want to suggest I had anything to do with it, I was a very young member of the General Assembly at that time. And I think of Luther Hodges, then Governor, as one person—if one person is to be selected as the father of this. Is there a person in the General Assembly or in government that you think of as the father of your institution?

Dr. HAMNER. I was not here, sir.—

Mr. VALENTINE. Or mother—or mother.

Dr. HAMNER. They were kind enough to allow me to come here about three years ago. But I understand that there were a number of people in the legislature who sort of fostered and looked out for developing the biotechnology. I think Governor Jim Hunt was the Governor at that time. I know Senator Kenneth Royal was certainly important. I know that—

Mr. VALENTINE. Those are some of the names I wanted you to mention.

Dr. HAMNER. Jerry Hancock was certainly—

Mr. VALENTINE. Now you are sure, before I go on to the next witness, that they did not have this thing in California before here, because I know Dana is going to ask you about that.

Dr. HAMNER. Well I can tell you what I think happened in California, but I will wait for that question.

Mr. ROHRABACHER. We have got some research like this going on in California.

Mr. VALENTINE. I know that, but beginning in 1912 is what I am talking about.

[Laughter.]

Mr. VALENTINE. Mr. Marcuson, I have heard briefly—a question of you and then the others, so as to get on to my colleague—I have heard about technology transfer now for a number of years and I have heard about the—and I think maybe been a small part of the government's efforts to encourage technology. But for the first time I think at a public forum I come face to face with the transferee.

Tell us briefly how that process—here was an invention, here was a concept, here was a new thing that was patentable and indeed patented. And this thing had come into being as a result of cooperation that involved academia, the federal government, the taxpayers—how was your company selected, how did you get the process?

Mr. MARCUSON. Basically through good old-fashioned hard work, hard work in the sense that the people that preceded me had identified the poultry business as a specific area where the fruits of biotechnology were not being applied in terms of any other food animal production or certainly crop production. So that niche was identified and then again through hard work in libraries at N.C. State, contacts that they had with people at the USDA, to try to understand what might be applied to poultry, and it was through that effort that the work that Dr. Sharma had done at East Lansing, Michigan was identified. A lot of thought went into the understanding of the process and what would need to be done to make it a real commercial kind of technology. And that came down to the process of devising an automated injection device. There is something in excess of six billion broilers produced in this country every year, each one of those is inoculated in a semi-automatic way but each one of those little birds is picked up by hand.

So it was a combination of a decent opportunity, hard work in terms of trying to understand whether or not relevant technology could be applied to that and then the process of investing time and money to take it through to commercialization.

Mr. VALENTINE. Is your stock publicly traded?

Mr. MARCUSON. We may be shortly, sir.

Mr. VALENTINE. What percentage of the stock does North Carolina State University own? You mentioned the number of shares.

Mr. MARCUSON. Yes, it would be a very small percentage, somewhere in the order of probably three-tenths, four-tenths of a percent.

Mr. VALENTINE. Dr. Reisner, do you believe that the conflicts between academic researchers and the industrial and applied researchers can be overcome by institutions such as the Biotechnology Center or do we need more of a major overhaul that involves the way we teach researchers?

Dr. REISNER. Oh, I think there has been a lot of exaggeration about the conflict. I think if one were talking to people on an engineering faculty, you would find that there have been relatively good relations between faculty and industry for the last 80-90 years. In fact, most of our industrial technology really did in fact grow out of a university start. I think one of the problems though is that it is very hard for the industrial scientist to get together with the academic scientist, there is really sort of no neutral ground. When it happens, it happens sort of by accident or it happens because of an organization like Dr. Hamner's Biotechnology Center. You really need a place that makes an overt effort to bring the two together.

Scientists working for any of the companies that have been represented here are just as fine scientists, they are just as interested in finding out basic truths as those scientists who work in universities. Perhaps one set is a little bit more goal oriented, perhaps the other set would really benefit at times from being a little bit more goal oriented. so I think just by getting people together, a lot of the misunderstanding does in fact go away.

I think just to expand a little bit on what Mr. Marcuson said, I think one of the real problems is that you were very lucky, you found the technology, but how much technology is there at universities, how many excellent ideas are there all over the world, in North Carolina and in California. But they are just sitting there because people do not know about them, it is not publicized. I think that is terrible because in fact there is really a tremendous loss of what could power new industrial development, just by lack of communication.

Mr. VALENTINE. It is gratifying to face somebody who quotes you correctly. You were well-prepared. I appreciate that though because I go to—I say that sort of thing about the business agenda to chambers of commerce and other groups at every opportunity and sometimes a friend of mine who works for me will say well, why do you need to keep on saying that. And I—we hear about the business agenda, you know, you know what the business agenda means, usually it means concern about the statute involving parental leave, it means opposition to the increased minimum wage, it means opposition to no-strike legislation. And I think for this state more so than any place I can think of, it ought to mean improvement in the quality of public education. I feel that as a kind of a personal crusade because it just makes me cringe—I know it is easy for one politician to give other politicians advice—when one sees what can be accomplished in this state, what has been accom-

plished in this institution because of the priorities that people in positions of leadership had. What we were able to do here with the system of higher education, the university system. And yet there are counties in my Congressional District where the state of illiteracy approaches that of Third World countries. And I just think that if we were able somehow to put some of this—not being selective, not cutting back on these other initiatives, but with additional tax money if it took it, to concentrate on this area of public education, what a—in other words, how great it would be if all our state looked like this area and functioned like this. Not that all of my District is not perfect, you understand.

But Dr. Lehmann, one final question and then I will yield to my colleague from California, our visitor. What do you feel about the public perception in this area? Dr. Hamner talked about it briefly. You are talking about things, and certainly the part of your company that is located in North Carolina, headquartered here, you are talking about things to do to crop land. How do you feel about that and what part does the public perception play in the situation in your company, the way you look at the future and how you operate presently?

Dr. LEHMANN. You know, if I take segments of time, if I would go back two to four years, I would say maybe it was quite a bit different than it is today. It might be that I am more of an optimist today than I was before, but I think that the technology and biotechnology has come along the last few years with field test progress, with demonstration plots on biotechnology so that in the case of farm folks who happen to see the benefits of that, they can walk out and say yeah, gee, that looks a lot like any other plant that I have seen before in the field, maybe a little more healthy and that is good, and with a minor modification with recombitant DNA. So I think we have made progress on public perception for the agricultural areas, considerably, but I would say that is also in the plant protection side too, because we work on recombitant microbes that will be, you know, environmentally compatible and used as part of integrated pest management, some would say "softer chemicals", I think in some cases would be compatible with those.

You know, as we move that way and become more conscious, I think we are stewards of that type of environment. So I would say the public perception is getting better, I think it is getting better particularly in many elements of the United States, but that does not mean we do not have big challenges and problems that we have got to address and we are trying to address. I am just saying that as you move the pendulum, it has been encouraging the last few years. And part of that has been on the progress of the science itself.

Mr. VALENTINE. You did not bring anything with you today that would kill Johnson grass, did you? I have got some on my farm—go ahead, excuse me.

Dr. LEHMANN. A little bit off the record—we have just your answer for that.

[Laughter.]

Dr. LEHMANN. And it comes in a little bitty tea bag about that big and it will cover about two to three acres.

Mr. VALENTINE. Well I am glad to hear that. Of course the birds will bring it back in.

Dr. LEHMANN. Keep in mind the name Beacon.

Mr. VALENTINE. Great. I have got a little farm in Nash County. I asked the question of one of my farm buddies down there a few years ago and you might be surprised at his advice. He said the only way you can deal with Johnson grass is move away from it.

Dr. LEHMANN. I think that was true until last summer.

[Laughter.]

Mr. ROHRABACHER. Maybe you will not need some of that ulcer medicine if you get some of this Johnson grass stuff.

Mr. Marcuson, are we going to have chickens about that big and Colonel Sanders is going to be having breasts that are that big?

Mr. MARCUSON. No, I do not think so.

Mr. VALENTINE. Stamped "made in North Carolina".

[Laughter.]

Mr. MARCUSON. And turkeys as well. I do not think so. What we will have is chickens which get to the proper weight, the desirable weight, quite possibly with less fat and more meat tissue, quite possibly five to six days sooner than they do at the present time. And hopefully a healthier bird that will be much more acceptable to the consumer than what we have got today.

Mr. ROHRABACHER. And is all of that due—or is all of this improvement that you expect going to be accomplished via the mass processing of chickens as we see them today or is this something that can be done that will basically affect chickens outside of that mass processing?

Mr. MARCUSON. I would think that the technology probably will be useful in both areas. Depending upon the commercial return though, which I suspect will continue to be greater in the mass processing area, that is where the technology would be adopted first. But I would not see anything that could strain its ability to work outside the mass area.

Mr. ROHRABACHER. Well let us put it this way. I can understand that when you have developed a new way of inoculating the bird so that it will be healthy—that is understandable—but I know that when I go to other countries, I notice that their chickens—you know, when you have chicken in a restaurant, especially down in Mexico and places where I spend a lot of time, the chicken really is not anywhere near as good as what we have here in the United States.

Mr. VALENTINE. They come from cock fights.

[Laughter.]

Mr. ROHRABACHER. But are we going to make a profit here in the United States by developing this stuff in a way that it will actually improve the chickens in other countries? I guess that is what I am getting at.

Mr. MARCUSON. From an export standpoint or just—

Mr. ROHRABACHER. No, no.

Mr. MARCUSON. —from the technology being useful other places as well?

Mr. ROHRABACHER. Is what you are developing salable in other places of the world?

Mr. MARCUSON. Absolutely, absolutely. You find that the poultry industry in this country has got a tremendous degree of integration in that the top ten producers produce something like 60 percent, 65 percent of the broiler birds in the United States. That same thing is occurring in Europe and in certain countries in Asia, Japan, specifically Thailand. Where you have a developed, integrated production process as well as a retailing and distribution process for the end product, we find that our technology would be very, very appropriate for.

Mr. ROHRABACHER. Okay, now are we going to then—I guess what I am coming down to, the bottom line of it, are we going to make, is our country going to make, through your efforts and efforts like those of your company, are we going to make a profit, a certain amount of millions of dollars, tens of millions, hundreds of millions of dollars, and in the end the world is going to have a better chicken?

Mr. MARCUSON. Absolutely, absolutely.

Mr. ROHRABACHER. When we are trying to develop these types of innovations, and we just heard that 7000 patents are waiting, do you think our Patent Office—is this a major stumbling block to this type of innovation?

Mr. MARCUSON. Yeah, I think so, in that you lose commercial market time, if you will, either through the delay in the Patent Office and/or the regulatory path. Both of those cut down on the length of time that you have to take a product to the market and sell it in an aggressive manner and build market share and generate revenues.

I would say that the delay in either case can be critical to the ultimate success of what a company like Embrex is trying to do.

Mr. ROHRABACHER. I do not know much about the patent office of your international competitors, but for example, the Japanese and other people who might be coming into competition with you. Do they have these kinds of delays in Japan, or do you know?

Mr. MARCUSON. Why do you not speak to that?

Dr. LEHMANN. I cannot speak to that, I do not know about the European. I know that most of us when we file patents file in several offices worldwide, but the delay, the focus has been here. I think our focus has been here because the technology has developed in the last few years so rapidly here, so we sense and feel it here. Also the richness of our markets here, that we really want to stay here.

Mr. ROHRABACHER. What about antitrust laws, have they gotten in the way at all—I mean we know we have got the states now encouraging companies to come in. Is there a problem with companies working together to develop biotechnology?

Mr. MARCUSON. Certainly that has not been the case.

Dr. LEHMANN. I have not heard about it, no. You know, I would say that I am new to this process in some respects, I am from a seed company and have been working with seeds for the biotech element, but I have been amazingly encouraged by the cooperation and the relationships, not only among companies in the area as the technology develops, which is we are all in this together, you would expect that, but also from the public sector, the universities, the cooperation there.

We fund a lot of university projects. Not only do we fund the university projects, as most of our competitors do too, because a lot of the technology base has been there, the basic technology. In addition to that, we have post-doc programs where we bring the post-docs from the university into our labs for a year or two, knowing that they will probably go somewhere else after that, but that is part of the development and training, a relationship. In addition to just the investment in the post-docs, we have a lecture series where we bring in people from the universities every month and sometimes more often than once a month, to keep the contact going. Because as we try to capitalize upon the technology, you know, you have really got to keep in mind where it might be popping up next and it is hard to anticipate that because it is moving pretty quickly.

Mr. ROHRABACHER. Well in the future, and as you mentioned, we do have a major deficit problem. The indebtedness of the United States, it is projected that in the 1992 budget, we will go—we are now going to have an indebtedness increase of $426 billion. Which to make that a little bit more realistic to you, that means from now on for every year for the rest of my life, there will be a budget item in the budget that will be about $35 billion just to spend on the interest for this year's increase in the debt. And it is a little bit overwhelming.

However, with that type of budget constraint, that does not mean that there are not things that we cannot do. And as we are talking about here, there are things that we can do besides give grants and things. There are things—government can do its job better, government can make sure that you do not have these type of delays in the Patent Office and government can make sure that, as your elected officials, can try to see that the regulatory climate does not stifle what you are trying to do. And also, you have already—you are demonstrating for the rest of the country how we can put to better use the money that is spent in education so that it is working in a cooperative spirit that ends up helping everybody out, education and business.

So I appreciate the chance to talk to you today and I appreciate your testimony.

Mr. VALENTINE. Thank you gentlemen very much. We are going to take five minutes here. We will be right back.

[Recess.]

Mr. VALENTINE. Our next panel, emphasizing high performance computing and electronics, consists of Mr. Larry D. Huffman, Manager of Resource Planning, IBM; Dr. Richard Jones, Executive Vice President of BroadBand Technologies, and Dr. Larry Lee, Vice President for Supercomputing, NC Supercomputing Center.

Welcome, gentlemen. Your statements will appear in the record as submitted to us. We would appreciate it if you would summarize.

Mr. Huffman.

STATEMENTS OF LARRY D. HUFFMAN, MANAGER OF RESOURCE PLANNING, IBM; DR. J. RICHARD JONES, EXECUTIVE VICE PRESIDENT, BROADBAND TECHNOLOGIES; DR. LARRY LEE, VICE PRESIDENT FOR SUPERCOMPUTING, NC SUPERCOMPUTING CENTER

Mr. HUFFMAN. Thank you, Mr. Chairman. I am Larry Huffman, Manager of Resource Planning and Business Operations at IBM Corporation's Research Triangle Park facility. My company and I appreciate your invitation to give our views on the computer industry and its position with regard to global competitiveness.

In the interest of establishing a local perspective, let me summarize the scope of our operations here in the Research Triangle Park. We started the establishment here in 1965, very small in scope, and we found such favorable conditions for IBM operations that today, North Carolina ranks third after only California and New York, in the number of IBM employees. Here in the Triangle, we employ in excess of 11,000 people who work in six million square feet of floor space, comprised of 55 buildings. We manufacture hardware from two-ton communication controllers to desktop computers and we also produce the software that enables our customers to control and maintain their computer networks.

Now let me move to the national picture, the scope of the electronics industry in the United States. Although the electronics industry is one of the newest major industries in the United States, it is the largest industrial employer in the country. Its work force totals 2.6 million people, its activities contribute roughly $300 billion a year to the United States' economy.

There are three primary subsections of our industry. The head and shoulders leader is computers, followed by semiconductors and software production. There is enormous cross-over effect between the computer industry and almost every other industry in America.

The computer industry is equally important to our national defense posture. Of the 22 technologies that the Pentagon considers critical to national security, 13 are related to computer systems.

I am sure you understand my point. The value of a healthy and energetic electronics sector cannot be viewed in narrow terms.

The computer industry, though still young, is without question a key pillar of America's economic structure. The primary question is, is the pillar sound? Can it continue to bear the weight of global competition?

We have a number of able competitors around the world, all of them from countries that view electronics as the key to sustained economic growth. In the six year period from 1983 to 1989, the United States' share of the world computer systems market fell from 60 percent to 40 percent. Where did our market share go? Japanese firms took almost three-quarters of it, Europe gained the rest.

In spite of enormous efforts to maintain technological leadership, we continue to lose market share.

You have to understand a problem before you can fix it. Our industry has identified and ranked the technologies most critical to the future competitiveness of the United States' computer systems industry. This review found that the United States lags behind the

rest of the world in nine of the 16 technologies that are most crucial to the future competitiveness of the American computer industry. Interestingly, we lag in the more fundamental and capital intensive technologies, such as micro electronics, integrated circuit fabrication equipment and facilities and manufacturing technologies. We are also behind in product-related technologies which include optical storage, displays and hard-copy technology.

There is good news. We still hold the lead in technologies that are less capital intensive, technologies that have, heretofore, been treated as secondary targets by our offshore competitors.

The bad news is those competitors are undertaking massive programs to close the gaps. Examples of these technologies are software engineering, applications technology and computer or central processor architecture.

In the interest of a businesslike approach to this problem, we must ask does it really matter that the United States is lagging behind? I think the answer is clearly yes. Our entire industry has a stake in strengthening the competitiveness of American industry, thereby strengthening our economy and enhancing United States or worldwide market opportunities. Any other approach would be irresponsible.

Thus, it is our goal to foster a global technology environment in which we are independent of foreign competitors for critical technologies. The outcome we seek is a global balance of strength in key technologies.

How do we achieve this balance? The starting point extends far beyond our factories and development laboratories. If we are to maintain balance with our Asian trading partners, we must attend to certain fundamentals. Without ranking them in any particular order, I would like to list the following:

Education. Our nation offers its students an inadequate education system where student have little interest in the technical subjects required to support advancements in science, technology and engineering.

In our industries we find outdated business processes where research, development and manufacturing often are performed sequentially with little interaction. If the Japanese have taught us anything, it is the value of a synergistic approach making incremental improvements to research, development and manufacturing.

United States industry has been slow to focus on quality. In Japan, the customer is king, quality is a religion.

Industry structure also is important. With a few exceptions, the United States electronics industry is far less vertically and horizontally integrated than its Japanese or European competitors. Furthermore, our industry has historically been independent and entrepreneurial in nature.

Our competitors employ broader business structures that allow them greater economies of scale and the ability to think in terms of long-range goals rather than short-range profits. Such well-integrated industries have greater access to patient capital, and they offer broader and deeper structures for nurturing technological development and then applying that technology to multiple product applications.

I hope that I have shown that we grasp the seriousness of the threats to our industry and now we can get about the task of fixing it.

American industry must work smarter and plan for the long range, yet focus on the complete satisfaction of every customer and the perfect quality of every product unit. These changes of attitude and process are underway in leading companies throughout the United States.

Now what is the proper role of government in encouraging such adjustments and maintaining an atmosphere in which United States companies can maximize their individual competitiveness?

First and foremost, government has a responsibility to provide industry with a business environment that promotes rather than inhibits technological development and deployment. Government has the responsibility to continually assess the business environment relative to the environments experienced by our global economic competitors.

Where imbalances exist, government has a responsibility to correct those imbalances through means such as:

(1) encouraging the availability of capital at a competitive cost;

(2) adopting antitrust laws that reflect global realities;

(3) creating tax policies that promote research, development and investment, and

(4) strongly enforcing laws that protect American industry against patent infringements.

Likewise, there are some policies that we would like to see government oppose. Policies such as investment restrictions, non-tariff trade barriers and other trade distorting measures and unreasonable restrictions on participation of foreign companies in cooperative research and development initiatives.

In addition to these specific policies, it would be beneficial for government to become increasingly and directly supportive of technology efforts aimed at bolstering commerce.

For our part, IBM is committed to working with governments and industry worldwide in strengthening technological and manufacturing infrastructures. We seek a global balance of technological excellence in which no single economic power can hold competitors hostage to technological domination.

Thank you for permitting me to make these observations. My company and I are honored to be involved in your examination of these matters.

[The prepared statement of Mr. Huffman follows:]

TESTIMONY
MAY 6, 1991
LARRY D. HUFFMAN
HOUSE COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY

THANK YOU, MR. CHAIRMAN. I AM LARRY HUFFMAN, MANAGER OF RESOURCE PLANNING AND BUSINESS OPERATIONS, AT IBM CORPORATION'S RESEARCH TRIANGLE PARK SITE. MY COMPANY AND I APPRECIATE YOUR INVITATION TO GIVE OUR VIEWS ON THE U.S. COMPUTER INDUSTRY AND ITS POSITION RELATIVE TO ITS GLOBAL COMPETITIVENESS.

IN THE INTEREST OF ESTABLISHING A LOCAL PERSPECTIVE, LET ME SUMMARIZE THE SCOPE OF OUR OPERATIONS HERE IN THE RESEARCH TRIANGLE PARK AREA. IN 1965 WE ESTABLISHED A SMALL OPERATION IN THE RALEIGH AREA. WE FOUND SUCH FAVORABLE CONDITIONS THAT TODAY NORTH CAROLINA RANKS THIRD, AFTER ONLY CALIFORNIA AND NEW YORK, IN NUMBER OF IBM EMPLOYEES. HERE IN THE TRIANGLE WE EMPLOY 11,500 PEOPLE, WHO WORK IN SIX MILLION FEET OF FLOOR SPACE IN 55 BUILDINGS. WE MANUFACTURE HARDWARE FROM TWO-TON CONTROLLERS TO DESKTOP COMPUTERS. AND WE PRODUCE THE SOFTWARE THAT ENABLES OUR CUSTOMERS TO CONTROL AND MAINTAIN THEIR GIANT COMPUTER NETWORKS.

IN SPITE OF THE SCOPE OF OUR OPERATIONS HERE, OUR RTP ACTIVITY STILL IS ONLY A SMALL PART OF THE HUGE U.S. ELECTRONICS INDUSTRY. THAT INDUSTRY INCLUDES THE PRODUCTION, DISTRIBUTION, AND SERVICING OF ELECTRONIC COMPUTERS, DATA STORAGE DEVICES, CONTROLLERS, TERMINALS AND OTHER ATTACHED EQUIPMENT, AND THE SOFTWARE THAT MAKES OUR HARDWARE PRODUCTS PRODUCTIVE.

ALTHOUGH THE ELECTRONICS INDUSTRY IS ONE OF THE NEWEST MAJOR INDUSTRIES IN THE U.S., IT IS THE LARGEST INDUSTRIAL EMPLOYER IN AMERICA. ITS WORK FORCE TOTALS 2.6 MILLION PEOPLE; ITS ACTIVITIES CONTRIBUTE ROUGHLY $300 BILLION A YEAR TO THE U.S. ECONOMY.

THERE IS ENORMOUS CROSSOVER EFFECT BETWEEN THE COMPUTER INDUSTRY AND ALMOST EVERY OTHER INDUSTRY IN AMERICA. OUR PRODUCTS HAVE MAJOR IMPACT ON AUTOMOBILES, AIRPLANES, BANK MACHINES, MEDICAL SCANNING DEVICES --- THE LIST IS SO ENDLESS, IT WOULD BE EASIER TO THINK OF THINGS NOT DEPENDENT ON ELECTRONICS.

THE COMPUTER INDUSTRY IS EQUALLY IMPORTANT TO OUR NATIONAL DEFENSE POSTURE. OUR SOPHISTICATED ARSENAL WOULD BE IMPOSSIBLE WITHOUT COMPUTER SYSTEMS AND ELECTRONIC COMPONENTS. OF THE 22 TECHNOLOGIES THAT THE PENTAGON CONSIDERS CRITICAL TO NATIONAL SECURITY, 13 ARE RELATED TO COMPUTER SYSTEMS.

I AM SURE YOU UNDERSTAND THE POINT. MY PURPOSE IN STATING IT IS TO SUGGEST THAT THE VALUE OF A HEALTHY AND ENERGETIC ELECTRONICS SECTOR CANNOT BE VIEWED IN NARROW TERMS.

THE COMPUTER INDUSTRY, THOUGH STILL YOUNG, IS WITHOUT QUESTION A KEY PILLAR OF AMERICA'S ECONOMIC STRUCTURE. IS THE PILLAR SOUND? CAN IT CONTINUE TO BEAR THE WEIGHT AS OTHER PILLARS GROAN WITH THE STRAIN OF GLOBAL COMPETITION? WHAT IS THE STATE OF THE COMPUTER INDUSTRY?

WE HAVE A GREAT NUMBER OF ABLE COMPETITORS AROUND THE WORLD --- ALL OF THEM FROM COUNTRIES THAT VIEW ELECTRONICS AS THE KEY TO SUSTAINED ECONOMIC GROWTH. IN THE SIX YEAR PERIOD OF 1983 TO 1989, THE U.S. SHARE OF THE WORLD COMPUTER SYSTEMS MARKET FELL FROM 60 PERCENT TO 40 PERCENT. WHERE DID OUR MARKET SHARE GO? ASIAN FIRMS TOOK ALMOST THREE QUARTERS OF IT --- EUROPE GAINED THE REST.

WHY ARE WE LOSING POSITION? IS OUR INDUSTRY SO SHORT SIGHTED THAT WE STARVE OUR RESEARCH AND DEVELOPMENT EFFORTS? THAT IS HARDLY THE CASE.

THE COMPUTER INDUSTRY PERFORMS TWENTY-ONE PERCENT OF ALL AMERICAN, PRIVATE-SECTOR RESEARCH AND DEVELOPMENT. WHEN YOU COMBINE THE COMPUTER INDUSTRY WITH THE ELECTRONICS INDUSTRY, THE TWO REPRESENT THIRTY PERCENT OF ALL PRIVATE RESEARCH AND DEVELOPMENT IN THE U.S.

HOW DOES THAT COMPARE WITH OTHER HIGH-TECH INDUSTRIES? OUR R&D INVESTMENT IS FIVE TIMES THAT OF THE AEROSPACE INDUSTRY, THREE TIMES THE EXPENDITURE OF HEALTH CARE FIRMS, AND FOUR TIMES THAT OF THE CHEMICALS INDUSTRY.

IN SPITE OF ENORMOUS EFFORT TO MAINTAIN TECHNOLOGICAL LEADERSHIP, WE CONTINUE TO LOSE MARKET SHARE.

FIRST, U.S. TECHNOLOGICAL SUPREMACY IS NOT A BIRTH RIGHT. LET ME OFFER A LITTLE PERSPECTIVE. PRIOR TO WORLD WAR TWO, GERMANY AND BRITAIN --- NOT THE U.S. ---- WERE THE BREAKERS OF NEW GROUND IN ELECTRONICS. AFTER THE WAR, THE U.S. LED THE WAY. OUR COUNTRY'S LEADERSHIP, TO SOME EXTENT, WAS A RESULT OF THE MISFORTUNES OF OTHERS.

OUR MAJOR COMPETITORS WERE EXHAUSTED OR BROKEN BY WAR, LEAVING OUR ENTIRE HEMISPHERE RELATIVELY UNTOUCHED BY IMPORTS. OUR ECONOMY WAS SUPERCHARGED FROM YEARS OF CHURNING OUT WAR GOODS. AND WE HAD THE BENEFIT OF SUPERIOR SCIENTIFIC TALENT IN THE FORM OF MANY CELEBRATED IMMIGRANTS WHO SOUGHT REFUGE HERE.

WE HAD AN ENORMOUS ADVANTAGE. THESE CIRCUMSTANCES COULDN'T PREVAIL FOREVER, AND THEY HAVEN'T. TODAY THE INTERNATIONAL POSITION OF THE UNITED STATES ELECTRONICS INDUSTRY IS SLIPPING.

SOME OF THIS SLIPPAGE COULD BE EXPECTED. SOME OF THIS LOSS MAY EVEN BE INEVITABLE. BUT OUR INDUSTRY IS DETERMINED TO NEITHER IGNORE NOR UNDER-RATE THIS TREND.

YOU HAVE TO UNDERSTAND A PROBLEM BEFORE YOU CAN FIX IT. IN THAT SPIRIT, ELEVEN LEADING COMPUTER INDUSTRY CHIEF EXECUTIVE OFFICERS --- INCLUDING OUR CEO --- HAVE FORMED AN ORGANIZATION CALLED THE "COMPUTER SYSTEMS POLICY PROJECT" --- CSPP. EARLY IN THE LIFE OF CSPP, ITS MEMBERS ASKED THEIR FIRMS' CHIEF TECHNOLOGISTS TO COOPERATE IN AN EFFORT TO IDENTIFY AND RANK OUR COMPETITIVE STRENGTH IN THE TECHNOLOGIES MOST CRITICAL TO THE FUTURE COMPETITIVENESS OF THE U.S. COMPUTER SYSTEMS INDUSTRY.

THIS REVIEW FOUND THAT THE UNITED STATES LAGS BEHIND THE REST OF THE WORLD IN NINE OF THE SIXTEEN TECHNOLOGIES THAT ARE MOST CRUCIAL TO THE FUTURE COMPETITIVENESS OF THE AMERICAN COMPUTER INDUSTRY.

WE LAG IN THE MORE FUNDAMENTAL AND CAPITAL-INTENSIVE TECHNOLOGIES SUCH AS:

MICROELECTRONICS

INTEGRATED CIRCUIT FABRICATION EQUIPMENT AND FACILITIES AND MANUFACTURING TECHNOLOGIES

WE ARE BEHIND IN PRODUCT-RELATED TECHNOLOGIES INCLUDING:

OPTICAL STORAGE

DISPLAYS

AND HARD-COPY TECHNOLOGY

THE GOOD NEWS IS, WE STILL LEAD THE WORLD IN TECHNOLOGIES THAT ARE LESS CAPITAL INTENSIVE, INCLUDING CRITICAL SOFTWARE TECHNOLOGIES. BUT OUR LEADERSHIP IN THESE SOFTWARE AND COMPUTER-ARCHITECTURE RELATED TECHNOLOGIES IS UNDER ATTACK BY OUR COMPETITORS. THEY RECOGNIZE THAT THEY ARE KEY TO SUCCESS IN OUR INDUSTRY.

IN THE INTEREST OF A BUSINESSLIKE APPROACH TO THIS PROBLEM, WE MUST ASK --- DOES IT REALLY MATTER THAT THE U.S. IS LAGGING BEHIND? SOME ARGUE THAT GLOBAL CORPORATIONS SUCH AS IBM HAVE LITTLE TO FEAR. AFTER ALL, WE PROCURE OUR RAW MATERIALS AND OUR CAPITAL INTERNATIONALLY, AND AT THE LOWEST POSSIBLE PRICE. THEREFORE, IT IS ARGUED, WE SHOULD HAVE LITTLE CONCERN OVER VARIOUS COMPETITIVE FLUCTUATIONS AROUND THE WORLD.

THESE SAME CRITICS ARGUE THAT OUR JOB IS TO MAXIMIZE SHAREHOLDER RETURNS, NOT TO ADVANCE NATIONAL GOALS. IN OUR VIEW, THESE GOALS ARE NOT MUTUALLY EXCLUSIVE. OUR ENTIRE INDUSTRY HAS A STAKE IN STRENGTHENING THE COMPETITIVENESS OF AMERICAN INDUSTRY, THEREBY STRENGTHENING OUR ECONOMY AND ENHANCING U.S. AND WORLDWIDE MARKET OPPORTUNITIES. OUR EFFORTS TO STRENGTHEN OUR INDUSTRY ARE, THEREFORE, GOOD FOR OUR NATION <u>AND</u> GOOD FOR IBM.

IN SO DOING, OUR GOAL IS TO FOSTER A GLOBAL TECHNOLOGY ENVIRONMENT THAT WILL AVOID OVER-DEPENDENCY ON KEY FOREIGN COMPETITORS FOR CRITICAL TECHNOLOGIES. THE OUTCOME WE SEEK IS A GLOBAL BALANCE OF STRENGTH IN THOSE CRITICAL TECHNOLOGIES.

HOW DO WE ACHIEVE THIS BALANCE? THE STARTING POINT EXTENDS FAR BEYOND OUR FACTORIES AND DEVELOPMENT LABS. IF WE ARE TO MAINTAIN BALANCE WITH OUR FOREIGN TRADING PARTNERS, WE MUST ATTEND TO CERTAIN FUNDAMENTALS. WITHOUT RANKING THEM IN ANY PARTICULAR ORDER, I WOULD LIST THE FOLLOWING:

-EDUCATION. OUR NATION'S EDUCATION SYSTEM MUST BE DRAMATICALLY IMPROVED. FOUR THOUSAND CHILDREN DROP OUT OF SCHOOL EACH WEEK, AND THOSE WHO REMAIN HAVE LITTLE INTEREST IN THE TECHNICAL SUBJECTS REQUIRED TO SUPPORT ADVANCEMENTS IN SCIENCE, TECHNOLOGY AND ENGINEERING. OUR CEO IS CHAIRING A BUSINESS ROUND TABLE EDUCATION TASK FORCE THAT IS BRINGING CEOs AND GOVERNORS TOGETHER TO ADDRESS THIS CRITICAL PROBLEM.

-IN OUR INDUSTRIES, WE FIND OUTDATED PROCESSES WHERE RESEARCH, DEVELOPMENT, AND MANUFACTURING OFTEN ARE PERFORMED SEQUENTIALLY WITH LITTLE INTERACTION. IF THE JAPANESE HAVE TAUGHT US ANYTHING, IT IS THE VALUE OF A SYNERGISTIC APPROACH TO RESEARCH, DEVELOPMENT AND MANUFACTURING, FOCUSED ON INCREMENTAL IMPROVEMENTS OF PRODUCTS.

-U.S. INDUSTRY HAS BEEN SLOW TO FOCUS ON QUALITY. IN JAPAN THE CUSTOMER IS KING AND QUALITY IS A RELIGION.

-INDUSTRIAL STRUCTURE ALSO IS IMPORTANT. WITH A FEW EXCEPTIONS, THE U.,S. ELECTRONIC INDUSTRY IS FAR LESS VERTICALLY AND HORIZONTALLY INTEGRATED THAN ITS JAPANESE OR EUROPEAN COMPETITORS. FURTHERMORE, OUR INDUSTRY HAS BEEN INDEPENDENT, ENTREPRENEURIAL, AND LITIGIOUS TO A FAULT.

-OUR COMPETITORS EMPLOY BROADER BUSINESS STRUCTURES THAT ALLOW THEM GREATER ECONOMIES OF SCALE, AND THE ABILITY TO THINK IN TERMS OF LONG-RANGE GOALS RATHER THAN SHORT-RANGE PROFITS. SUCH WELL-INTEGRATED INDUSTRIES HAVE GREATER ACCESS TO PATIENT CAPITAL, AND THEY OFFER BROADER AND DEEPER STRUCTURES FOR NURTURING TECHNOLOGICAL DEVELOPMENT AND THEN APPLYING THAT TECHNOLOGY TO MULTIPLE PRODUCT APPLICATIONS.

I HOPE I HAVE SHOWN THAT WE UNDERSTAND THE PROBLEM, AND WE GRASP THE SERIOUSNESS OF THE THREATS TO OUR INDUSTRY. NOW WE CAN GET ABOUT THE TASK OF FIXING IT.

WE CANNOT REVERSE THESE TRENDS BY THE SHEER WEIGHT OF MORE PROGRAMS, MORE STUDY COMMITTEES, AND MORE MEETINGS. WE NEED POSITIVE ACTION THAT BREAKS THE CHAINS "OF BUSINESS AS USUAL." THERE'S AN OLD SAYING AT IBM --- "WE DON'T NEED TO WORK HARDER, WE NEED TO WORK SMARTER." AMERICAN INDUSTRY MUST WORK SMARTER. WE MUST PLAN WITH A LONG-RANGE VIEW, YET ACT EACH DAY ON THE PREMISE THAT OUR DESTINY RESTS ON THE COMPLETE SATISFACTION OF EVERY CUSTOMER AND THE PERFECT QUALITY OF EVERY PRODUCT UNIT.

THESE CHANGES OF ATTITUDE AND PROCESS ARE UNDERWAY IN LEADING COMPANIES THROUGHOUT THE UNITED STATES. BUT WHAT IS THE PROPER ROLE OF GOVERNMENT IN ENCOURAGING SUCH ADJUSTMENTS AND MAINTAINING AN ATMOSPHERE IN WHICH U.S. COMPANIES CAN MAXIMIZE THEIR INDIVIDUAL COMPETITIVENESS?

FIRST AND FOREMOST, GOVERNMENT HAS A RESPONSIBILITY TO PROVIDE INDUSTRY WITH A BUSINESS ENVIRONMENT THAT PROMOTES --- RATHER THAN INHIBITS --- TECHNOLOGICAL DEVELOPMENT AND DEPLOYMENT. GOVERNMENT HAS THE RESPONSIBILITY TO CONTINUALLY ASSESS THE BUSINESS ENVIRONMENT RELATIVE TO THE ENVIRONMENTS OFFERED BY OUR GLOBAL ECONOMIC COMPETITORS.

WHERE IMBALANCES EXIST, GOVERNMENT HAS A RESPONSIBILITY TO CORRECT THOSE IMBALANCES THROUGH MEANS SUCH AS:

-ENCOURAGING THE AVAILABILITY OF CAPITAL AT A COMPETITIVE COST,

-ADOPTING ANTITRUST LAWS THAT REFLECT GLOBAL REALITIES,

-CREATING TAX POLICIES THAT PROMOTE RESEARCH, DEVELOPMENT AND INVESTMENT,

-AND STRONGLY ENFORCING LAWS THAT PROTECT AMERICAN INDUSTRY AGAINST PATENT INFRINGEMENTS.

LIKEWISE, THERE ARE SOME POLICIES THAT WE WOULD LIKE TO SEE GOVERNMENT OPPOSE --- POLICIES SUCH AS:

-INVESTMENT RESTRICTIONS

-NON-TARIFF TRADE BARRIERS AND OTHER TRADE-DISTORTING MEASURES

-AND, UNREASONABLE RESTRICTIONS ON PARTICIPATION OF FOREIGN COMPANIES IN COOPERATIVE RESEARCH AND DEVELOPMENT INITIATIVES.

IN ADDITION TO THESE SPECIFIC POLICIES, IT WOULD BE BENEFICIAL FOR GOVERNMENT TO BECOME INCREASINGLY AND DIRECTLY SUPPORTIVE OF TECHNOLOGICAL EFFORTS AIMED AT BOLSTERING COMMERCE. THIS TYPE OF ACTIVITY MAY BE QUESTIONED BY SOME WHO ARE RELUCTANT TO ALLOW U.S. PRACTICE TO EVOLVE, BUT IT IS NECESSARY BECAUSE GOVERNMENTS IN COMPETITIVE NATIONS ARE DOING IT, AND THEIR ECONOMY HAS PROSPERED AS A RESULT. THOUGH NOT A PANACEA, GOVERNMENTS OF MANY COUNTRIES WILL BE COMPELLED BY SELF INTEREST TO DEFINE NEW ROLES TO HELP LEVEL THE GLOBAL INDUSTRIAL PLAYING FIELD.

FOR OUR PART, IBM IS COMMITTED TO WORKING WITH GOVERNMENTS AND INDUSTRY WORLDWIDE, AND STRENGTHENING TECHNOLOGICAL AND MANUFACTURING INFRASTRUCTURES. WE SEEK A GLOBAL BALANCE OF TECHNOLOGICAL EXCELLENCE IN WHICH NO SINGLE ECONOMIC POWER CAN HOLD COMPETITORS HOSTAGE TO TECHNOLOGICAL DOMINATION.

THANK YOU FOR PERMITTING ME TO MAKE THESE OBSERVATIONS. MY COMPANY AND I ARE HONORED TO BE INVOLVED IN YOUR EXAMINATION OF THESE CRUCIAL MATTERS.

(END)

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Mr. VALENTINE. Thank you Mr. Huffman.

Dr. Jones.

Dr. JONES. Thank you for the opportunity to come and speak before this Committee.

I would like to notice that one of the things that I have heard today is one of the role that regulation can play in both a positive and negative sense in encouraging innovation in industries in the United States. And I am going to talk about that theme myself.

Before I address that though, I would like to give you a little bit of background about BroadBand Technologies. We are a venture financed communication products company founded in 1988 and we are developing fiber optic communication products that are used by telephone companies in their local loop and can also be used by cable television companies for their distribution systems.

The unique thing that we bring to the market is that we have designed our system for broadband communications capability. We have tried to look into the future and see what role fiber optics would play as a technology in communications applications, and rather than make it work in a hampered way or a hindered way, we have tried to design systems that will allow full broadband capability of fiber optics to be utilized. The systems that we have designed are capable of both telephony transmission, and in the jargon of our industry, telephony is referred to as "plain old telephone service" or POTS. We also provide other services, sometimes—

Mr. VALENTINE. That does not include that telephone like Andy Griffith has, the channel type thing, does it?

Dr. JONES. It could.

The other aspect as I mentioned of broadband services, those are sometimes called peculiar and novel services or PANS. So we are in the POTS and PANS business of broadband technologies.

One of the twists here is that our emphasis is on providing this technology for residential subscribers rather than business subscribers. Our feeling is that that aspect is being taken care of. We also have designed a system to provide a platform for transport of data and other services as they may be required.

What will occur when systems like ours are implemented is that residential and small business subscribers will have access to advanced telecommunications capability the way that large companies today have that access. This will provide access for the residential subscriber, access to advanced education and entertainment services in addition to the "life-line" services such as plain old telephone service that is provided today. In the parlance of our industry, we are referred to as fiber-in-the-loop products, FITL is the short—POTS, PANS and FITLs.

Mr. VALENTINE. Do you have a special department that creates all these names?

Dr. JONES. Our investors are not very happy about that, but they have an acronym department.

As I mentioned earlier, BroadBand Technologies is well differentiated in our marketplace because we offer this broadband capability. Specifically it is in the form of a switched digital video transport capability. That, as I said, differentiates us well in the marketplace. Most of our competitors have focused on analog technology

similar to that being deployed by cable television operators. But there has been recent activity in this switched digital video area, in CATV and in the high definition TV area that have begun to validate the approaches that we have taken as a company.

We have been successful to date in this emerging marketplace. Our system is being evaluated in field trials by five of the seven regional Bell operating companies. The regional Bell operating companies serve approximately 85 percent of the telephone lines in the United States. That is a fairly remarkable situation for a company, venture financed company, whose competitors include AT&T, Northern Telecom and other very much larger companies.

Our market situation is quite unique. Most people acknowledge the benefits technology like we have developed would have in improving national communications infrastructure, and of course that would be very helpful in improving national competitiveness and I will address that more later. The improvements that fiber-in-the-loop offer would facilitate—the improvements that this would facilitate are quite well recognized and documented. But in spite of that, no one communications provider has the mandate to deploy such systems.

Regulation constrains telephone companies from being in services other than just plain old telephone service. In contrast, early in the telecommunications industry, telephone companies were given the mandate for universal service and they received that in sort of a trade, I guess you would say, the regulatory body said you can have a monopoly if you will take service universally to the United States. Of course the benefit of that, I think, is widely recognized. But now it is time to change the regulation environment to allow for competition in local telephony.

I will give you a—part of the problem that telephone companies in general have now is that with regard to putting fiber in the loop, they have to justify this technology on the basis of cost equivalence with the present technology, copper-based, twisted wire. That is possible to do and one of the points that our company and other companies have made is that fiber optics can be cost competitive with POTS, with copper for POTS applications. But what is missing is a motivation to move the technology more quickly. If regulations were changed such that telephone companies could provide services beyond plain old telephone service, then they would be encouraged to deploy fiber more quickly. In fact, one particular telephone company has pointed out—this is Bell Atlantic—has pointed out that they would install fiber at a rate at least twice as fast if they had other business opportunities to pursue.

Now the same thing is true with cable television companies and other carriers in similar business. However, these—specifically the cable television industry—are in the business of providing entertainment rather than life-line services, and as a result their networks have been much more optimized for lower costs and for these kinds of services, the entertainment type of services. Those systems are broadcast oriented, they provide the same signal basically to all customers and they are not optimized for the interactive two-way kinds of services that future broadband network should have.

As I mentioned, what is needed is a regulatory environment that would encourage competition amongst these local communications providers which would lead to the deployment of broadband networks. For example, if telcos were allowed into the information services business, such as the delivery of entertainment video, the opportunity for new revenue would motivate this deployment of fiber in the loop. I will give you an example, which would be the entertainment entrepreneur, if you will. Today, a person with very narrowly focused entertainment services or entertainment programming is not able to deliver that service to residential subscribers. The biggest barrier is the cost of providing the network to bring that programming to the subscriber. As a result, a subscriber ends up with the most common denominator programming that could be made available. If there were a common carrier who provided carriage services to local—to residences—then an entrepreneur in the entertainment industry could bring this more narrowcast oriented entertainment and would not have to justify—would not have to invest the money to provide the delivery system, he could simply rent time on an existing delivery system provided by a common carrier such as a telephone company.

Mr. VALENTINE. Why does that sound strangely like competition for cable television? Is that what it is?

Dr. JONES. It would be competition for cable television, yes.

Mr. VALENTINE. More power to you and to us.

Dr. JONES. I think a more important example that an interactive broadband network would have on the education system. Let me use an example. Imagine a situation 25 years from now, a Japanese teenager sits down at her broadband terminal—just let me note parenthetically that Japan has committed to having a nationwide broadband communications network in place by the year 2015—this teenager sits down to search for examples of Voyager's photographs of Jupiter's moons. The reason I use this example is because that would require very high resolution photographs in order for this particular research project to be completed. Several examples are found, copies are printed, an analysis of the visual evidence of volcanic activity is completed in time for a mid-afternoon class, which is viewed on the same terminal. The assignment is submitted through a facsimile machine.

In the United States, a student faced with the same assignment gets in his car to drive to the library only to find that the needed book has been previously checked out. He drives to the school to attend class and report his failure to complete the assignment. The Japanese student has used tools of the information age to enhance her education. The American student has stayed with the tools of the industrial age, the car.

A further example is in the retraining of workers affected by the downturn of sunset industries. In Japan, mass re-education programs will be made available through information technology available to all. The cost of such programs in a non-information based society will be so daunting that they will not be put into place and as a result, the brick-and-mortar, face-to-face classroom approach that would be used in the United States will relegate the average worker to a job at McDonald's.

If we continue with the present communications policy, then the infrastructure of the United States will fall behind and the competitiveness will be affected.

Now I have talked about telephone companies being the mechanism for bringing this technology to improve competitiveness. The same could be true of cable television providers and other carriers. But I do want to point out that the goal is not a broadcast oriented entertainment driven network but rather a two-way switched broadband network that would require a fairly radical restructuring of the cable television network. But if those service providers are willing to do that, then so much the better. The result again of competition encouraging both parties to try and put such a network in place would be beneficial.

Let me summarize by saying that this is a vital issue for national competitiveness. Improving the communications infrastructure would have positive impacts on education, the environment, the cultural level of the population and the economy, to name a few areas. A well-known author, George Gilder, has written recently an article that appeared in the Harvard Business Review, it is called "Into the Telecosm" and this article very eloquently summarizes the arguments that I have tried to bring to this Committee. So I recommend the article for your review.

Once deployed nationwide, a broadband communications network becomes the ultimate tool for technology transfer. The purpose of this Committee is to examine mechanisms for technology transfer. A broadband network would do just that. The creative force of the individual can be brought on line from anywhere in the network. Engineers can work at home and access powerful computers in real time interactions to design state of the art technology. Students can have access to the best professors or data bases without leaving their home. Doctors could consult with non-collocated specialists while simultaneously viewing detailed x-rays to aid in patient diagnosis. And finally, viewers could select programming which rises above the lowest common denominator programming available today.

Thank you.

[The prepared statement of Dr. Jones follows:]

TESTIMONY TO THE HOUSE SUBCOMMITTEE ON TECHNOLOGY AND COMPETITIVENESS

Dr. J. Richard Jones
BroadBand Technologies, Inc.
Research Triangle Park, NC 27709

May 6, 1991

BACKGROUND

BroadBand Technologies, Inc. is a venture capital financed communication products company which was founded in 1988. We are developing fiber optic transmission systems for use in the telephone companies' local loop (or cable television companies' distribution systems). These systems are designed for broadband communications capability; both telephony (plain old telephone service - POTS) and video (CATV-like) signals are transported to residential subscriber's homes. In addition, a "platform" is provided for transport of data and other services that will be required in "electronic cottage" and small business applications. When implemented, our systems will allow residential and business subscribers to have access to advanced education and entertainment services in addition to "life-line" services such as POTS. In the parlance of our industry, our products are fiber-in-the-loop (FITL) systems.

We are well differentiated in our marketplace because we offer switched digital video capability, which is considered to have arrived a product generation earlier than expected. Recent activities in the CATV and high definition television (HDTV) marketplace indicate an emerging trend toward digital video technology.

We have achieved success to date in that our system is being evaluated in field trials by five of the seven Regional Bell Operating Companies (RBOCs). RBOCs serve approximately 85% of the telephone lines in the United States.

IMPACT ON INFRASTRUCTURE

Our market situation is unique. Most acknowledge the benefits technology like ours would have in improving the national communications infrastructure (with resulting improvements in national competitiveness). The improvements FITL would facilitate are widely recognized and well documented. In spite of that no one has the clear mandate to deploy such systems, no matter how beneficial they are considered to be. Telcos are constrained by regulations from providing information services (whether they be CATV, business, or educational services), so they are not motivated by the opportunity for new business to deploy FITL. In the past, Telcos have had the mandate for universal services and have had the motivation, from a regulatory point of view, to encourage them to achieve their mandate. With regard to FITL deployment, Telcos are in the situation of having to justify it on the basis of cost equivalence for POTS alone. While this can be achieved, additional motivation would be very helpful in accomplishing the goal of a broadband network. CATV providers are in the business of entertainment services and, therefore, do not have the business motivation to speculatively put in systems for applications beyond those they already know. Furthermore, their delivery systems are broadcast-oriented and, therefore, are not optimized for interactive two-way services that are a part of the envisioned network of the future.

What is needed is regulatory environment that encourages competition leading to the deployment of broadband networks. If, for example, Telcos were allowed in the information services business (such as delivery of entertainment video), the opportunity for new revenue would motivate deployment of FITL. Deployment of broadband FITL networks would encourage their use by other service providers (given that Telcos are encouraged through regulations to be common carriers). An example is the potential for the growth of specialized, non-common denominator, TV programming. A TV entrepreneur will be able to access a limited subscriber base cost effectively without the necessity of building a separate distribution network because one will be available from the local Telco, requiring only rental of the time required for viewing of the program.

A more important example is the impact that an interactive broadband network would have on the education system. Imagine the situation 25 years from now. A Japanese teenager sits down at her broadband terminal (Japan has committed to having a nationwide broadband communications network in place by the year 2015) to search for examples of Voyager's photographs of Jupiter's moons. Several examples are found, copies are printed and an analysis of the visual evidence of volcanic activity is completed in time for a mid-afternoon class, which is viewed from the same terminal. The assignment is submitted by fax. In the United States, a student faced with the same assignment gets in his car to drive to the library only to find that the needed book has been previously checked out. He drives on to school to attend class and report his failure to complete the assignment. The Japanese student has used the tools of the information age to enhance her education. The American student has been

restricted to the tools of the industrial age (the car). A further example is in the retraining of workers affected by the downturn of sunset industries. In Japan, mass re-education programs will be made available through information technology available to all. The cost of such programs in the "brick and mortar," face-to-face classroom approach used in the United States will relegate the average worker to a job at McDonald's. As long as we are limited to our current communications infrastructure the United States will continue to fall behind the better-informed, highly competitive Japanese.

Increased competition in the local loop could also motivate CATV and other carriers to upgrade their networks to carry voice and other data services. To achieve the desired goal of a broadband switched network would require radical changes in the CATV network of today. Simply doing what CATV operators are doing today (placing fiber in the feeder) is not sufficient to upgrade the communications infrastructure. However, if the appropriate changes were made, the resulting network would be similar to that mentioned above. Again, the result would be an improvement in the country's communications infrastructure with a consequent increase in competitiveness. Either way, through Telco expansion or other carrier expansion, the desired improvement in communications infrastructure is accomplished.

Some have argued that changing the regulatory environment will not result in improvements in infrastructure. We do not think this is a concern in light of Telcos' statements that they would build broadband networks if regulatory relief were granted (e.g. Bell Atlantic's chairman, Ray Smith, has made such a

statement). Regardless, what is there to loose? It seems clear that the positive impact of such a move is worth the risk.

SUMMARY

This is a vital issue for national competitiveness. Improving the communications infrastructure will have positive impacts on education, the environment, the cultural level of the population, and the economy, to name a few areas. George Gilder has eloquently elaborated on these topics in his recent article, "Into the Telecosm," in the Harvard Business Review. I recommend that article for your review.

Once deployed nationwide, a broadband communications network becomes the ultimate tool for technology transfer. The creative force of the individual can be brought "on line" from anywhere in the network. Engineers can work at home and access powerful computers in real time interactions to design state-of-the-art technology. Students can have access to the best professors or data bases without leaving their home. Doctors can consult with non-collocated specialists while simultaneously viewing detailed x-rays to aid in patient diagnosis. Viewers can select programing which rises above the lowest common denominator programing available today.

Mr. VALENTINE. Thank you, Dr. Jones.

Dr. Lee.

Dr. LEE. Thank you, Mr. Chairman, for this opportunity to comment on the role of high performance computing in national competitiveness.

The questions I am going to attempt to address this morning are the following: What has been the impact of high performance computing on scientific and engineering research? What is the potential value of high performance computing to increasing United States' industrial productivity and how can the barriers to industrial use of high performance computing be overcome?

In recent years, high performance computing has become an every day tool in scientific and engineering research. The result has been the creation of a new paradigm for conducting research—computational science. This is a method of scientific investigation that uses numerical techniques and high performance computers to test models and theories, and it extends the traditional methods of theoretical observation and laboratory experimentation.

In the 1980s, the National Science Foundation created a very successful infrastructure in scientific communications and computing. The NSF established five national supercomputing centers, one of which is the very forward looking and successful San Diego Supercomputing Center in California. They also established a national backbone network connecting the centers and a national network linking university researchers throughout the country to each other and to high performance computing. The results has been extraordinary. More than 15,000 university-based scientists and engineers have access to high performance computing and have developed the necessary skills to effectively access this technology. We can point to numerous scientific achievements, including a predictive model of air pollution disposition in the Los Angeles basin and an understanding of the structure of the human cold virus.

In the last few years, high performance computing has been successfully introduced into other federal agencies with research missions, such as the EPA and NIH. The North Carolina Supercomputing Center, NCSC, and the EPA have a cooperative agreement that seeks to find more efficient methods of developing and executing environmental models and analyzing results. In this partnership the EPA has access to NCSC's training and education programs, supercomputer systems and expertise in computational science and visualization.

I will give one more example—Enzyme Technology, Inc. is a small North Carolina company located in Research Triangle Park. It is in the business of using enzymes to promote desirable chemical reactions like sensing cholesterol in human blood or oxidizing pollutants in water. By having access to the expertise in computational science and the supercomputers at the Center, Enzyme Technology has increased the number of enzyme tests conducted each day from two to 20, a productivity gain of nearly 1000 percent. Needless to say, the President of the company is a strong supporter of high performance computing.

The next natural step, but still a very difficult one, is to develop a way to transfer the knowledge and experiences of current users

of high performance computing to a much broader sector of industry.

There is no question in my mind as to the value of high performance computing to industrial research and development efforts. From determining the physical, chemical and biological processes of new filtration agents, to predicting the performance of ship hull designs, high performance computing can play a crucial role in advancing the United States' competitive position in the global market. Access to high performance computing will enable companies to more quickly design products, to test prototypes, to simulate production and continue production refinement. Thus enabled, corporations will be more aggressive with product goals, have a shorter time span from concept design to market, and have a higher quality of product.

But one problem in some industry sectors is that there has been a tremendous investment in traditional research laboratories and thus there is, very naturally, a resistance to shift to computational science. It is possible that some leading industry sectors may become vulnerable to foreign competition that incorporates high performance computing more quickly into its R&D programs.

There are a number of perceived barriers that need to be overcome for American industry to use high performance computing. The cost of acquiring the hardware, software, expertise and space is non-trivial and can range from five to fifteen million dollars per year. There is also a large risk factor. Will an investment in this technology bring near-term dividends? Without a chance to experiment with high performance computing, corporations cannot easily be convinced that this technology has an immediate application to their research and development efforts.

And finally there is the question as to whether there is sufficient number of scientists trained in this technology to use it productively in the corporate research environment. Experts in computational science are a scarce resource and only exist today in significant numbers at national laboratories, supercomputing centers and universities.

I would like to propose a model to place high performance computing into the hands of the industrial users that will leverage on existing infrastructure. The use of pooled resources, human and computational, is the key. The model would be the establishment of consortia of corporations affiliated with high performance computing centers. The model could be established in any state or any collection of states. The members of a consortium might be for example in North Carolina, North Carolina corporations involved in biotechnology research, NIEHS and the Supercomputing Center here. The members would be linked by an advanced network such as CONCERT and would have access to the training, educational programs, computational science expertise and supercomputing resources of our Center.

If there were, for example, ten large corporations, each investing $250,000 per year and if the federal government matched this investment with a $2.5 million grant, this would leverage the state's $8 million per year investment in supercomputing and communications and provide the consortium members with the most advanced networking and high performance computing capability available

in the nation today. More importantly, the transfer of applications and technology from supercomputing and university resources to these corporations will happen naturally and effectively without the corporations needing to make an enormous investment, take large risks or create and implement a massive retraining program for corporate employees.

There are many other models that could be considered also. A relevant point is that high performance computing is increasingly important to R&D and that through cooperative government, university and industry programs, the perceived obstacles to industrial use can be overcome.

I urge the federal government to become a significant partner in transferring high performance computing to industry. The model of leveraging on existing infrastructure and providing matching support to consortia is a starting point.

Thank you.

[The prepared statement of Dr. Lee follows:]

A PERSPECTIVE ON THE ROLE OF HIGH PERFORMANCE COMPUTING IN NATIONAL COMPETITIVENESS

Testimony Delivered by
Lawrence A. Lee
North Carolina Supercomputing Center, Research Triangle Park, NC
Before the House Committee on Science, Space, and Technology
Subcommittee on Technology and Competitiveness
Monday, May 6, 1991

Thank you, Mr. Chairman and members of this committee, for this opportunity to comment on the role of high performance computing in national competitiveness. As someone who has seen high performance computing technology advance from its infancy in the 1970s to the exciting developments occurring today, and who has seen its applications grow and diversify to the point now that it can have a revolutionary positive impact on U. S. productivity and industrial competitiveness, I am very pleased to share my thoughts with this distinguished committee.

The questions I am going to attempt to address this morning are the following. What has been the impact of high performance computing on scientific and engineering research? What is the potential value of high performance computing to increasing U. S. industrial productivity? And how can the barriers to industrial use of high performance computing be overcome?

In recent years, high performance computing has become an everyday tool in scientific and engineering research at American universities. The result has been the creation of a new paradigm for conducting research - computational science. This is a method of scientific investigation that uses numerical techniques and high performance computers to test models and theories, and it extends the traditional methods of theoretical observation and laboratory experimentation.

In the 1970s and early 1980s, the Department of Energy and NASA incorporated supercomputing into their research laboratories for application to weapons design and aerodynamics/aerospace problems. These research programs have profited enormously by having access to this technology. The United States has maintained its lead in weapons design, intelligence, aircraft design, and space programs, due in part to access to high performance computing.

In the 1980s, a national infrastructure was created in scientific communications and computing that led to the very successful introduction of high performance computing into academia. The NSF established five national supercomputing centers, a backbone network connecting the centers, and a national network linking university-based researchers to each other and to high performance computers. The results

have been extraordinary. More than 15,000 university-based scientists and engineers across the nation have developed the necessary skills to use high performance computing in research. We can point to numerous scientific achievements, including a predictive model of air pollution dispersal in the Los Angeles basin and an understanding of the structure of the human cold virus. The national research network, NSFNET, has provided access to high performance computing resources for academic researchers, has fostered interdisciplinary collaborative research, and has provided for the exchange of knowledge. The federal government's plan to extend and expand the capabilities of the network is vital to the effort to widely disseminate high performance computing technology and applications.

In the last few years, high performance computing has been successfully introduced into other federal agencies with research missions, such as the EPA and NIH. The North Carolina Supercomputing Center (NCSC) and the EPA have a cooperative agreement that seeks to find more efficient methods of developing and executing environmental models and analyzing results. The Regional Acid Deposition Model (RADM) and Regional Oxidant Model (ROM) are two such models. The RADM takes meteorological and pollutant emissions data and estimates the concentrations of chemical pollutants in the atmosphere and their subsequent disposition.

The EPA and NCSC are also investigating the application of advanced scientific visualization techniques in enhancing the interpretation and evaluation of massive amounts of real environmental data and data obtained from model simulations. In the future, the EPA and NCSC will study the effectiveness on alternative architectures of certain computational methods and algorithms associated with environmental models. In this partnership, the EPA has access to NCSC's training and education programs, supercomputer systems, and expertise in computational science and visualization. These resources are the critical success factors. This partnership, I believe, is another important example of how to transfer the use of high performance computing to a research environment.

I will give one more example. Enzyme Technology, Inc., is a small North Carolina company located here in Research Triangle Park. It is in the business of using enzymes to promote desirable chemical reactions like sensing cholesterol in human blood or oxidizing pollutants in water. By having access to the expertise in computational science and the supercomputers at NCSC, Enzyme Technology has increased the number of enzyme tests conducted each day from 2 to 20, a productivity gain of 1000%. Needless to say, the president of the company is a strong supporter of the cooperative program with the NCSC.

The next natural step, but still a difficult one, is to develop a way to transfer the knowledge and experiences of current users of high performance computing to a much broader sector of industry.

There is no question, in my mind, as to the value of high performance computing to industrial research and development efforts. From determining the physical and

chemical processes of new chemical filtration agents, to predicting the performance of ship hull designs, high performance computing can play a crucial role in advancing the U. S.'s competitive position in the global market. Access to high performance computing will enable companies to more quickly design products, test prototypes, simulate production, and continue product refinement. Thus enabled, corporations will be more aggressive with product goals, have a shorter time span from concept design to market, and have a higher quality of product.

The Gartner Group has prepared a report for the Department of Energy entitled "High Performance Computing and Communications: Investment in American Competitiveness." This report estimates that the productivity improvements that can be gained by providing industry sectors with access to high performance computing range from 0.2 to 4.8% annually. These are very significant numbers.

But one problem in some industry sectors, like the pharmaceutical and chemical industry, is that there has been a tremendous investment in traditional research laboratories and thus there is, very naturally, a resistance to shift to computational science. It is possible that some leading industry sectors may become vulnerable to foreign competition that incorporates high performance computing more quickly into its R&D programs.

There are a number of perceived barriers that need to be overcome for American industry to use high performance computing. The cost of acquiring the hardware, software, expertise, and space is non-trivial and can range from $5 - 15M per year. There is also a large risk factor. Will an investment in this technology today bring near-term dividends? Without a chance to experiment with high performance computing, corporations cannot easily be convinced that this technology has an immediate application to their research and development efforts.

And finally there is the question as to whether there is a sufficient number of scientists trained in this technology to use it productively in the corporate research environment. Experts in computational science are a scarce resource and only exist in significant numbers at national laboratories, supercomputing centers, and universities. But their experience and expertise can be transferred to researchers in non-academic environments, as evidenced by the NCSC/EPA cooperative activity.

I would like to propose a model to place high performance computing into the hands of industrial users that will leverage on existing infrastructure. The use of pooled resources, human and computational, is the key. The model would be the establishment of consortia of corporations affiliated with high performance computing centers. The members of a consortium might be, for example, North Carolina corporations involved in biotechnology research, NIEHS, and the NCSC. The members would be linked by an advanced network such as CONCERT and would have access to the training, educational programs, computational science expertise, and supercomputing resources of NCSC.

If there were 10 corporations each investing $250,000 per year, and if the federal government matched this investment with a $2,500,000 grant, this would leverage the state's $8,000,000 per year investment in NCSC and CONCERT to provide the consortia with the most advanced networking and high performance computing capability available in the nation today. More importantly, the transfer of applications and technology from NCSC and university resources to these corporations will happen naturally and effectively without the corporations needing to make an enormous investment, take large risks, or create and implement a massive retraining program for corporate employees.

In summary,

- high performance computing has become a powerful tool for conducting research at national laboratories, universities, and some corporations;
- there is very convincing evidence that if American industry does not incorporate computational science into its R & D programs, it could become vulnerable to foreign competition that does use it;
- the barriers to industry use of computational science can be overcome by government/industry partnerships that leverage on the existing infrastructure in high performance computing; and
- introducing HPCC technology into corporate R & D will fundamentally change the way industrial research is conducted and will have a long-term, far-reaching impact on our competitive position in the global market.

Mr. VALENTINE. Thank you, Doctor. I appreciate all of you gentlemen.

Mr. Huffman, you stated that government should create tax policies that promote research, development and investment. Do you have anything in mind other than the investment tax credit?

Mr. HUFFMAN. That is the primary one. Let us make it self-perpetuating as opposed to 12 to 15 month extensions. That step would be of obvious benefit.

Mr. VALENTINE. I understood you to suggest certain fundamentals and it was my recollection that you suggested that these were fundamentals that needed attention, that they needed change or emphasis or some form of refurbishing. You talked about education and the lack of interaction between research and development and manufacturing and lack of focus on quality. And out of those it would see to me that all of them except education would be the responsibility of business and industry, where the government would have limited, if any, opportunity to become involved. Would you agree with that?

Mr. HUFFMAN. I would. The distinction that I would make is that we would suggest that government plays a very strong role in addressing what I will term environmental inequities between the form that we compete on versus foreign competition. I think clearly the other element that I highlighted is the responsibility of industry in general. Quality and price performance are the bare minimums to be successful. We have not done a very good job necessarily at addressing those items in the past and we have seen competitive advantage established, particularly out of the far east on that front.

The other point that I made had to do with the change in business processes. Technological development is wonderful, but if you cannot bring it to the marketplace quickly, timely, you have lost the advantage of leadership. And we in IBM have started to restructure such that we have technology development and subsystem development running in parallel with one another along with systems design. And we believe that that approach will allow us to dip into each hierarchal stream of technology as it becomes available and bring it to the marketplace as quickly as possible. Cycle times are extremely critical. Bringing it from the laboratory into the marketplace is absolutely critical.

In the case of personal systems which we manufacture here in the Research Triangle Park, that parallel development that I just described we think will allow us to bring new technology from the laboratory to the marketplace in six to nine months. And in the personal systems business, you clearly have to be able to do that, it is what our competitors are in fact doing.

Mr. VALENTINE. A few years ago, I remember someone coming to Committee and talking about a new and revolutionary concept in the way the government does business, a new idea. Do you know what it was? It was called pay-as-you-go. What happened to quality in this country? You pick up an old Sears, Roebuck catalog, somebody gave me one for Christmas, a 1903 Sears, Roebuck catalog, and on almost every item they are talking about quality, quality. If you bought a horse and buggy—not that I am quite that old, Dana, but it would last you for a lifetime. Now you buy an automobile

that is supposed to become obsolescent, it is supposed to wear out. Where did we slip into that type of situation where we now have to remind American business of quality. Rhetorical question, I do not—

Mr. HUFFMAN. Yes, obviously I do not have an answer specifically to the question. I will tell you that the area that you just touched on though becomes very much a cultural element in business and it is not just a product business, but it is also in services. And we have adopted an approach, and we try to be very, very careful inside the IBM Company to ensure that the program we introduced last year does not become another program of the year, because I think that to the extent we keep trying to roll one program into another program, you very quickly use up all the goodwill that perhaps you have established with people in the organization.

So we have clearly taken on a renewed emphasis and it is being demonstrated at the very top of the business with our chief executive officer right down to each and every employee, and it is something that you have to live day-in, day-out, you have to change your behavior if you really want to be successful in a mindset of almost perfect quality.

Mr. VALENTINE. Dr. Jones, when you—thank you, sir—you talked about the situation in Japan and the dream or plan to have every home connected with fiber optics. Now that involves doing things kind of the old-fashioned way, that involves putting a cable in the ground, does it not, digging a ditch every place?

Dr. JONES. Yes, it does.

Mr. VALENTINE. We are a severe geographic disadvantage, are we not, when it comes to hooking—tying together the nation of Japan and even all the islands, and doing that same thing in the United States. That would be one hellacious job in the United States, would it not?

Dr. JONES. It would be a large job, but you have in place some very large corporations, very large from an asset point of view, that normally turn that network over. There is a 20 to 30 year life cycle for telephone networks, so the telephone companies are refurbishing their network at the rate of three to five percent per year. So there is a natural kind of refurbishment that will take place where copper cables get replaced with fiber optic cables.

What I was trying to advocate is something where we actually would encourage them to speed that refurbishment up, give them a business reason to do that.

Mr. VALENTINE. The nation is fairly well hooked together with fiber optics, is it not? It is just a question of running it down every street, is that it?

Dr. JONES. Well we have got highways in place, superhighways in place. Many companies in the 1980s made it a priority to put this high-speed communications capability in place—MCI, U.S. Sprint popularized that in their television commercials. It also caused AT&T, the entrenched company, to move more quickly in putting that technology in place.

But that does not provide access for the residents. It really is for large businesses. It brings fiber optics to a place they call a point of presence within a city, and anyone who can bring transmission fa-

cilities from their facility to that point of presence can access the network. Large companies are in a position to pay for dedicated links and so forth so they can take advantage of that. But the residential subscriber of course is not in a position to do anything about that.

Mr. VALENTINE. You mentioned, Dr. Jones, the SBIR program. Other than the size of the effort, do you have any other problems with implementation?

Dr. JONES. SBIR?

Mr. VALENTINE. Small Business Innovative Research program.

Dr. JONES. I do not think I mentioned that, sorry.

Mr. VALENTINE. Okay, that belongs in another panel. There will be some staff positions open.

[Laughter.]

Mr. VALENTINE. Dr. Lee, I know what we are talking about. These—the federal matching investment dollars, of course there is a problem as to where they would originate—how would that be judged? What kind of peer review system do you envision?

Dr. LEE. Well it is a question as to what agency would be responsible for conducting such a review and responsibility for allocating funds for a program like that. But I envision representatives from industry, representatives from the scientific community, representatives from technology, communications, networking and so on, getting together and taking a look at the proposals and judging which ideas have the best chance of transferring this technology to industry. And I think this can be done relatively quickly. I think people are out there that understand the value of the technology to industry and I think the community is ready to judge as to who should get that type of funding and who should not.

Mr. VALENTINE. Mr. Rohrabacher.

Mr. ROHRABACHER. Well first, I would like to note that I do not believe that you could really buy a horse that would last a lifetime, even at the turn of the century, but I will say—

Mr. VALENTINE. No, no, I meant the buggy, I did not mean the horse.

Mr. ROHRABACHER. Well you said a horse and buggy, but I will say that after these gentlemen—

Mr. VALENTINE. You are picking on me.

Mr. ROHRABACHER. —on the panel prior to this panel, where they have the biotech all in progress, they are going to have the biotech in the future, we might be able to have a horse that will last a lifetime. That is just a thought.

[Laughter.]

Mr. ROHRABACHER. Dr. Jones, I would appreciate it if you would send me the article by George Gilder that you referred to.

Dr. JONES. I have a copy with me.

Mr. ROHRABACHER. I would appreciate it if I could take that with me and read it in the airplane. I would appreciate that.

Do you—we have been mentioning the competitive factor in Japan. One thing that I always like to focus on is the fact that the Japanese tend to—they tend to encourage cooperation among companies. Do you find the antitrust laws in some way is hindering American competition with Japan?

Mr. HUFFMAN. I will take first crack at that. Yes. In this sense, today we have programs and activities in place that foster or promote joint development. When we start talking about joint manufacturing and now we are talking about the deployment of technology—how can you take a given technology and utilize it across industries. I think that the current laws which were designed for protecting a domestic marketplace, do not exactly serve us well when we think about a global marketplace.

Mr. ROHRABACHER. In fact, many of the antitrust laws that are affecting your industry were actually brought in at a time when the horse and buggy was the major mode of transportation and railroads was the ultimate technology.

Mr. HUFFMAN. Yes.

Mr. ROHRABACHER. The—just—do either of you have a note on that?

[No response.]

Mr. ROHRABACHER. What is the rate of capital gains tax in Japan? Zero? The answer is zero.

Thank you very much.

Mr. HUFFMAN. Thank you.

Mr. VALENTINE. Do any of you know what the total tax burden is in Japan?

Thank you gentlemen very, very much.

Our next and final panel is on the question of establishing a favorable environment for technology transfer and consists of Mr. James Roberson, President, Research Triangle Park Foundation; Mr. Bill Riley, Jr., Executive Director, Triangle Universities Licensing Consortium and Mr. Steven Burke, Director of Education and Public Affairs at the NC Biotechnology Center.

Welcome, gentlemen, your statements will appear in the record as presented to us and we would ask you if you would please summarize.

Mr. Roberson.

STATEMENTS OF JAMES ROBERSON, PRESIDENT, RESEARCH TRIANGLE PARK FOUNDATION; WILLIAM RILEY, JR., EXECUTIVE DIRECTOR, TRIANGLE UNIVERSITIES LICENSING CONSORTIUM AND W. STEVEN BURKE, DIRECTOR OF EDUCATION AND PUBLIC AFFAIRS, NC BIOTECHNOLOGY CENTER

Mr. ROBERSON. Thank you, Mr. Chairman.

On behalf of the Research Triangle Park, as the owner—Research Triangle Foundation, as the owner and developer of the Research Triangle Park, I want to welcome you here to what many consider to be the most successful research park in the country.

Since founding in 1959, Research Triangle Park has become a model for research parks not only in the United States, but throughout the world. Scarcely a week goes by, as a matter of fact, that we are not visited by some study team that wants to know how did Research Triangle Park become so successful. Just this month we will have teams from Finland, Taiwan and Singapore visiting the park.

What they are going to find out is that the park has attracted more than 50 major research facilities, that those 50 research fa-

cilities employ about 33,000 people, makes us the 17th largest city in North Carolina on a daily basis, and they occupy about 13 million square feet of office and laboratory space.

What they will learn about in terms of why this park has been so successful is first and foremost its location within just a few minutes drive of three major research universities: Duke University in Durham; University of North Carolina in Chapel Hill and North Carolina State University in Raleigh. These universities created the notion of the research park, the idea of a research park or a center for corporate research originated at Chapel Hill. And so one of the things that has characterized Research Triangle Park has been the openness and the willingness of the academic researcher to work with the corporate researcher. And that is a culture that is not present every place in the United States or indeed around the world.

There are some 500 people working in the park that carry adjunct professorships at one of the three or perhaps more than one of the three Triangle universities, and there are probably on the magnitude of 2000 or 2500 people on the faculty and staff of the universities that have some sort of an ongoing relationship with corporations in the Park, so there is honest synergy.

The second thing that our visitors learn is that the State of North Carolina has created a political or, if you will, business climate that is extremely attractive in the Park. You have already heard from representatives of the North Carolina Biotechnology Center and will here again from Steven, and of course here we are in the offices of the NCNC, formerly the Microelectronics Center of North Carolina and you heard from Dr. Lee from the Supercomputer Center. This kind of investment I think is unique among the states in the country in terms of science-based economic development. The state has made tremendous investment and that, I think, is reflected by the companies that are here in the Park.

The third reason for the Park's success is that there has been an environment created by the Research Triangle Foundation that has said this is to be a science park, this is to be a research park, not an industrial park with an emphasis on technology, but truly a science park. And while manufacturing is permitted in the park, it is manufacturing that must be directly tied to research that is ongoing in the park. So as a result, what has happened is there has been the creation of a community of scholars in this park that work in a physical environment that fosters creativity. Only 15 percent of the typical site purchased by a company for a major research facility can be occupied by a building, 85 percent then is to remain open space, parking lots and that sort of thing. So it truly is a delightful, beautiful park and one we think that is conducive to research.

The fourth reason for the success of the Park is the quality of life that is available throughout the Research Triangle area. Housing is available, it is plentiful, it is affordable. Local schools in the three counties are good, they are getting better. Cultural and athletic events are available year-round as is golf and tennis. We are two hours from the ocean with the completion of the interstate to Wilmington now and three and a half hours or so from the mountains and we have excellent transportation, particularly with the

advent of the hub by American Airlines at Raleigh-Durham International.

A lot of the visitors that will come to the park are somewhat surprised, given our success, that we are not full. But the truth of the matter is, we have developed about 60 percent of the Park, 40 percent is yet to be developed and in order to do that we conduct a pretty extensive program of marketing, both nationally and internationally. We have targeted specific kinds of industries, we make personal calls on executives there. We do a limited amount of advertising and conduct a direct mail campaign to selected industry groups, and our marketing efforts I think have provided us with some insights on the role the federal government can play in encouraging the creation of corporate research and development.

Today we see a much higher level of interest on the part of European and Asian companies than we do American companies. I think the problem is that we deal all too often in this country with quarterly earning statements, that CEOs are preoccupied with how that next quarterly earning statement is going to look and not as preoccupied with where their company is going to be in ten years or 15 years or even 20 years.

We find exactly the opposite when we are talking with Japanese companies or European companies that are considering major research facilities in the United States. And I would say that a substantial portion of those who are looking at a facility certainly on the eastern half of the United States look at Research Triangle Park. What we are talking about is really a culture that somehow needs to be changed.

I think I would make two recommendations to this Subcommittee. One is—and you have heard it many times—is the need to make the research and development credits permanent so that businesses can plan on them, they know they are going to be there next year and the year after and the year after, instead of dealing with this constant problem of having it reinstituted each year.

And look at how our government regulations influence the investment of major funds. Most of the savings, as you know, in this country have accumulated in pension funds that are administered by very, very significant investment bankers who decide how the state employees pension funds in North Carolina, as an example, are going to be invested. And one of the regulations that seems to be pervasive in protection of those funds is the "prudent man" rule that essentially says that you have to make a buy or sell decision based entirely on the conditions that exist today and do not look at what conditions might be in three years or five years or ten years. A company that has a certain amount of new technology in the works in that pipeline that ultimately has great potential once it reaches commercialization, receives virtually no credit for that. Certainly we would not suggest that employee pension funds not be protected, but we would suggest that there needs to be a look at the rules and regulations that are associated with that investment, ERISA if you will, that requires companies to make buy or sell decisions, or pension managers rather, to make buy or sell decisions based on current conditions, not really looking at potential.

There are a number of comments that are contained in my written testimony that I am not going to go into. I am certainly no

expert on tax policy. But it seems to me that it is obvious that the federal government needs to make R&D tax credits permanent, that you need to encourage private funds to make long-term investment and of course increase federal funding for non-defense research and development.

I want to thank you for the opportunity of being here today. We appreciate again you being in the Park, we think you are in one of the real centers of research in the United States. Thank you, sir.

[The prepared statement of Mr. Roberson follows:]

JAMES O. ROBERSON, PRESIDENT

RESEARCH TRIANGLE FOUNDATION OF NORTH CAROLINA

MAY 6, 1991

Good morning Mr. Chairman and members of the House of Representatives' Subcommittee in Technology and Competitiveness.

On behalf of the Research Triangle Foundation of North Carolina - the owners and developers of the Research Triangle Park - I want to officially welcome you to America's largest and, in the opinion of many, most successful research park.

Since its founding in 1959, Research Triangle Park has become a model for developing research parks throughout the United States and in many parts of the world.

Scarcely a week goes by that we are not visited by a study group wanting to learn how to emulate Research Triangle Park's success. Just this month, as an example, we will host study groups from Finland, Taiwan and Singapore.

These groups want to learn why more than 50 major research and development facilities are located in the Park - facilities which occupy over 13 million square feet of office and laboratory space, employ some 33,000 people, and represent over $2 billion in capital investment.
What they will learn is that Research Triangle Park's success is related to several important factors:

First, and of primary importance, is its location within only a few minutes drive of three major research universities; Duke University in Durham, North Carolina State University in Raleigh and the University of North Carolina in Chapel Hill. These Triangle universities display a very open attitude toward collaboration with researchers from the business world.

The synergetic effort of corporate researchers with academic researchers is undeniable. More than 500 people working in research facilities in the Park carry adjunct professorships at one or more of the Triangle Universities. We estimate more than 2,000

members of the universities' faculty and staff have some type of consulting arrangements with organizations in the Park.

Secondly, our visitors will learn that the State of North Carolina and local governments have worked together to create a political (or business) environment which is extremely attractive.

Particularly important to the Park and many of its companies is the commitment of the State of North Carolina to science-based economic development. This facility in which we are located today, MCNC (formerly known as the Microelectronics Center of North Carolina) is the first example of the state's commitment; the others are the North Carolina Biotechnology Center and the North Carolina Supercomputing Center.

The third major reason for Research Triangle Park's success is the unique research environment which the Foundation has created here. Research Triangle Park is truly a research park; every organization located here is involved in research. While manufacturing is permitted, it must be manufacturing that is directly related to research which is on going in the Park.

As a result, Research Triangle Park has become a community of scholars, scholars who are working daily on transferring technology into the market place. This community works in a physical environment which fosters creativity: there is respect for the land with large open spaces featuring forests of pines and hard woods, buildings located appropriately on landscaped sites, with careful consideration given to high esthetic standards.

The fourth reason for Research Triangle Park's success is the quality of life that is available throughout the Research Triangle area. Housing is available, is plentiful and affordable. Local schools are good and getting better. Cultural and athletic events are available year round, as is golf and tennis. We are only two hours from the ocean and three and a half to four hours from the mountains. We have excellent transportation by air and automobile and are close to a myriad of outdoor recreational facilities.

Because of the Park's success over the past 32 years, many visitors are surprised to learn that only 60 percent of the Park is developed. Of the Park's total 6800 acres, only about 4000 acres have been

developed. Some 2800 acres remain available for major research facilities.

Because the Foundation funds its activities exclusively from the proceeds of land sales in the Park, (we have never been beneficiaries of tax support from any governmental source), we have an active, and expensive, comprehensive marketing program.

We systemically make personal calls on targeted industries in the U.S. and abroad to encourage companies to consider Research Triangle Park when they are evaluating sites for new research and development facilities.

We also conduct a direct mail campaign to selected industry groups and do a limited amount of advertising to these same targeted groups to reinforce the image of Research Triangle Park as the preferred location for R&D facilities.

The results of our marketing efforts provide a significant lesson, we believe, into the role of the federal government in encouraging the creation of corporate research and development and the competitiveness of U.S. companies in a global economy.

Today, we see a much higher level of interest in creating new R&D facilities on the part of European and Asian companies than American companies.

There is a much more appreciated view of the value of long term, often highly risky, investment in research by European and Asian, particularly Japanese, companies than by their American counterparts.

Although there are significant exceptions, the bulk of American companies apparently are managed by executives who are much more concerned by the effects of their next quarterly earnings statement than by the potential positive results of investments in R&D that may not produce new products or processes for ten or fifteen or even twenty years.

One of the significant reasons for American companies to have such a short range view of investment is the atmosphere for R&D created by the Federal Government.

As an example, for many years now, tax credits for R&D facilities have been renewed on a year-to-year basis. There is always an air of uncertainty regarding the future of tax credits for corporate research and development.

Since many companies will spend well over a year planning, evaluating and implementing construction of a new R&D facility, they need assurance that the Federal tax credits for R&D are available for the long term.

Just as corporate commitment to long-term investment is critical to this country's competitiveness, so is a long term commitment by the Federal government to taxing policy.

Mr. Chairman, you will no doubt recall the comments of Representative Mike Andrews of Texas when he spoke to members of the Southern Technology Council in Washington on January 23.

Representative Andrews said: "The Federal government could play a huge role in stimulating high-tech manufacturing performance by enacting a permanent research and development tax credit."

He went on to say: "This credit, temporarily extended several times in recent years, will expire again at the end of this year. This start-and-stop approach of Congress wreaks havoc on a company's long-term planning for research and development. We are undermining our own goal of long-term investment."

We concur completely with Representative Andrews' view!

Equally important to long-term investment in America's future is the Federal governments' policy on other tax credits and economic incentives.

The volatility of the United States federal tax system, as compared to the more consistent, stable Japanese tax system, may frustrate long-term investment planning of United States based research and development. Nevertheless, current federal tax rates in the United States are lower than rates historically and the tax credit for "research and experimentation" expenses related to qualified research" remain as viable incentive.

However, the proposed treasury regulations related to I.R.C. 44, issued in May of 1989, do not provide definitive guidelines on the availability of the credit for research and development expenditures related to activities such as software development.

Without a stable tax structure and clear guidelines on qualification for tax incentives smaller companies face an onerous recordkeeping burden and auditing costs.

Other tax incentives should be considered to support the early stages of research and development. Such incentives might include educational tax credits for participation in continuing or advanced educational programs which concentrate on skills necessary for technological development.

The Tax Reform Act of 1986 repealed the availability of the investment tax credit. Some states, including North Carolina, provide a tax credit and/or deduction for investments in certain "qualifying technology-based companies."

Financial resources, other than governmental funding and grants, for technological development comes from three basic sources: (1) institutional investors such as financial institutions and profit-sharing plans, (ii) corporations, and (iii) venture capitalists.

Most investors from each of the three segments qualify as "accredited investors", which facilitates private placements and sale of securities to raise capital needed for research and development. However, tax investment incentives such as additional tax investment credits, reductions in capital gains rates or a one-time exemption from income tax of a lump sum amount of capital gains (i.e. maximum of $500,000) for investment in "qualifying companies" may provide additional incentives for these three groups to devote the dollars and time to research and development needed to reach ultimate commercialization.

The financial institutions have some regulatory restrictions under the Glass-Steagall Act on direct and indirect investment in securities. These restrictions have been eroded by numerous exceptions carved from the basic prohibition.

Other institutional investors, including financial institutions acting in a fiduciary capacity and fiduciaries of qualified retirement plans, may be subject to certain restrictions on the type of their investments and the amount invested in any particular entity.

These funds are required by law to be governed by a "prudent man rule" that requires pension managers to look only at immediate gains in making buy or sell decisions - with virtually no opportunity to look at the future potential of a public company's investments in the future, investments that often are concentrated in research and development. Obviously, pension funds need to be protected, but perhaps it is time to review federal mandates on long-term versus short term investments.

I do not pretend any expertise in taxing policy.

But common sense tells me that until the Federal government focuses its tax and other policies with respect to long-term, speculative and often highly risky investments in research and development, American companies will be at a major competitive disadvantage with their aggressive off shore competitors. R&D simply cannot be treated as conventional investment.

America still boasts the best "cutting edge" technology in the world, but our ability to maintain that advantage is largely dependent on the policies of the Federal government. Facilities housing applied research activities need to be given permanent special tax treatment if we are going to move technology out of the lab and into the marketplace.

The relatively recent decision to have Federal labs actively develop plans to share their technology is to be much applauded.

But, there remains a great deal to be done in focusing expanded Federal research on non-defense areas including microelectronics, telecommunications, biotechnology and ecology and the environment.

The identification in April by the Office of Science and Technology of nationally critical process and project technologies must be acted upon.

The OSTP's list of technologies must not be ignored or dismissed as a guise for creating a national industrial policy.

We urge your support of efforts to focus our nation's attention on opportunities to exploit American leadership in these technologies to keep or regain our competitiveness.

In summary, then, I urge this committee to actively develop and sponsor Federal tax policy that will permit American businesses to meet the global competitiveness challenge.

Those policies should make R&D tax credits permanent; should encourage private funds to make long-term investment; and, should increase Federal funding for non-defense research and development.

In conclusion, I again want to thank the committee members for your efforts to improve this nation's competitiveness.
Your efforts to make the Federal government more active in helping American companies effectively meet their global competition is greatly appreciated.

We wish you great success and invite you to revisit Research Triangle Park in future years to see some of the fruits of your labor.

Mr. VALENTINE. Thank you, sir.

Mr. Riley.

Mr. RILEY. Chairman Valentine, Congressman Rohrabacher, I appreciate the opportunity to present some of my opinions regarding the present university/industry technology transfer environment. It should be emphasized that these are my own views and not intended to reflect the opinions of the three universities that are members of my consortium.

The Triangle Universities Licensing Consortium [TULCO) was established in 1987 by Duke University, North Carolina State University and the University of North Carolina at Chapel Hill. Its primary objective is to help these universities transfer its technologies into public use. Although TULCO is governed entirely by the universities and has to operate within their policies, it operates independently. Its primary responsibility is to represent the universities in marketing their investments to industry. Each of the universities retains control of their own patent policies and signs all the agreements when they are finally negotiated. TULCO's professional staff—three—all have technical backgrounds and had prior industrial marketing experience before joining the organization. This is considered to help greatly in understanding both the university and the industrial viewpoints and thus assist in bridging the so-called university/industrial gap.

Today in my opinion, federal laws and regulations do not significantly impede the transfer of university technology to industry. Since the passage of Public Law 96-517 and subsequently 98-620 in the early 1980s, the situation has dramatically improved. There are still complaints, as there are when you have to deal with any government agency, but in my opinion, it would be unfair to say that federal laws and regulations are a negative, a serious negative, in technology transfer today.

Presently, a more serious problem is that there is often a lack of mutual understanding between the universities and industry. This university gap can be characterized by extremes. At one end, there is the university attitude that its technology is absolutely essential to industrial success and is therefore worth a very large percentage of the profit that may result. At the other end, there is the industrial attitude that based on the size of investment required to bring new ideas to the market, the university contribution is relatively insignificant. This dichotomy is much more prevalent when working with some industries than others.

At one end of the continuum there are the older established industries, although some may have been founded originally on new technology, it is unlikely that their success has been heavily dependent on a regular inflow of technology from outside sources. Historically, most of their innovations were in the form of improvements to existing technology.

Times have changed in recent years. More and more of these companies are now looking to universities to help them keep pace with foreign and domestic competition. However, when they do sponsor university research, they often tend to view it as temporary work for hire, and adamantly resist paying a fair royalty based on profits generated by any patentable technology that may result. Also, some find it difficult to understand that universities

cannot accept a number of restrictions that are common in industry. For instance, not permitting publication of research results.

At the other end of the spectrum there are many of the newer companies, such as biotechnology and superconductivity that are presently heavily dependent on university-generated technology and in some cases were founded on such. A significant number of their management are likely to have academic backgrounds and recognize that their future could be heavily dependent on the constant inflow of new ideas from universities. Such companies tend to be much more understanding of universities attitudes and requirements.

Although today there are situations where one or the other of the above propositions will be valid, it is not normally the case. As usual, the truth lies in between and can best be reconciled by communication and understanding. Some in industry must abandon the idea that sponsoring research at a university is no different than hiring an office replacement for a day. Others in the academic community will have to give up the idea that all of their ideas commercialized by industry are worth millions. When that is the case, the parties will still have many agreements, but they will understand the other's perspective and with few exceptions be able to agree on reasonable compromises. Such compromises are becoming more frequent and I believe the situation will continue to improve in the future as many more companies realize that university generated technology can be an important factor in their future. The key is more and better communications. The situation is improving at this time and can be accelerated by environments such as the one we are meeting in today, Research Triangle Park.

This community of academia and industry have done much to encourage the mutual access and communication required to encourage the frequent collaboration necessary to bridge the gap.

Thank you.

[The prepared statement of Mr. Riley follows:]

UNIVERSITY/INDUSTRY TECHNOLOGY TRANSFER ENVIRONMENT

Statement by
Wm. E. Riley, Jr.
Executive Director
Triangle Universities Licensing Consortium(TULCO)
to
U.S. House of Representatives
Subcommittee on Technology and Competitiveness

May 6, 1991

Mr. Chairman, Members of the Subcommittee:

I appreciate the opportunity to present some of my opinions regarding the present university-industry technology transfer situation. It should be emphasized that these are my own views and are not intended to reflect the opinions of the three universities that are members of the consortium.

The Triangle Universities Licensing Consortium(TULCO) was established in 1987 by Duke University, North Carolina State University, and The University of North Carolina at Chapel Hill. It's primary objective is to help these universities be more effective in getting their intellectual property into public use. Although TULCO is governed entirely by the universities and functions within their policies, it is an independent operation. Its primary responsibility is to represent the universities in marketing their inventions to industry. Each of the universities retains control of their own patent policies and all agreements are signed by them. TULCO's professional staff(3) have technical backgrounds and had prior industrial marketing experience. This helps in understanding both the university and industrial viewpoints and thus assists in bridging the so called university-industry "gap" which, although not universal, often exists.

Today, Federal laws and regulations do not significantly impede the transfer of university technology to industry. Since the passage of P.L. 96-517 and 98-620 by Congress in the early 1980's, the situation has dramatically improved. There are still complaints, as there are always likely to be when dealing with Government agencies, however, it would be very unfair to say today that the Federal Government is a serious negative in the transfer of university generated technology. Presently, a more serious problem is that there is often a lack of mutual understanding between universities and industry.

The university-industry "gap" can be characterized by extremes. At one end there is the university attitude that its technology is absolutely essential to industrial success and is therefore worth a very large percentage of any profits that may result. At the other end, there is the industrial attitude that based on the size of the investment required to bring new ideas to the market, the university contribution is relatively insignificant. This dichotomy is much more prevalent when working with some industries than others. At one end of the continuum there are the older established industries. Although some may have been originally founded on a new technology, it is unlikely that their success has been heavily dependent on a regular inflow of technology from outside sources. Historically, most of their innovations were in the form of improvements to existing technologies. Times have changed in recent years. More and more of these companies are now looking to universities to help them keep pace with foreign domestic competition. However, when they do sponsor university research, they often tend to view it as temporary work-for-hire and adamantly resist paying a fair royalty based on profits generated by any patentable technologies that may result. Also, some find it difficult to understand that universities cannot accept a number of restrictions that are not uncommon in industry, eg.not permitting publication of research results.

At the other end of the spectrum, there are many of the newer industries such as biotechnology and superconductivity that are presently heavily dependent on university generated technology, and in some cases were founded on such. A significant number of their management are likely to have academic backgrounds and recognize that their future could be heavily dependent on a constant inflow of new ideas from universities. Such companies tend to be much more understanding of university attitudes and requirements.

Although today there are situations where one or the other of the above propositions will be valid, it is not normally the case. As usual, the truth usually lies in between and can be best reconciled by communication and understanding. Some in industry must abandon the idea that sponsoring research at a university is no different than hiring a temporary office replacement for a day. Others in the academic community will have to give up the idea that all of their ideas commercialized by industry are worth millions. When that is the case the parties will still have many disagreements, but they will understand the other perspective and, with few exceptions, be able to agree on reasonable compromises.

Such compromises are becoming more frequent and I believe the situation will continue to improve in the future as many more companies realize that university generated technology can be an important factor in their future. The key is more and better communications. The situation is improving at this time and can be accelerated by environments such as the one in which we are meeting today, Research Triangle Park. This community of academia and industry has done much to encourage the mutual access and communication required to encourage the frequent collaboration necessary to bridge the "gap".

Mr. VALENTINE. Thank you, sir.

Mr. Burke.

Mr. BURKE. Mr. Valentine, Mr. Rohrabacher, I join others in evidencing pleasure that you came here today, and I also thank Dr. Sigmon for bringing us so effectively together.

In his earlier statement, Dr. Hamner furnished introductory information about the North Carolina Biotechnology Center. I will build on that information to inform of conclusions we have reached about effective technology transfer and about technological development.

Our Center early began to implement a major premise, that we could not assure effective and steady development of biotechnology in North Carolina unless we approached that development comprehensively. As such, our activities assisted all points on the continuum along which technology develops, beginning with research and ending with products and commercial gain. We also soon recognized that this continuum does not operate in a void but instead within the geography, culture and 6.3 million people of this state.

The Center works then earnestly to address the questions and needs that inevitably arise when new science meets ongoing society. We attend to education and training at all levels from middle school to university. We initiated development of consensus state legislation on the release into the environment of genetically engineered organisms, legislation drafted by and satisfying industrial, corporate and research points of view and we have worked to identify and respond to the ethical, societal and policy issues attendant to a technology that deals with life.

Implementing this comprehensive approach and learning from the results of doing so had led us to a central conclusion. Technological development in general and technology transfer in specific must be seen from the beginning within the fullest possible societal context. Technology transfer can no longer be seen just as a tidy movement from science to industry to application. Technology transfer must be considered instead more broadly, as the movement from science to many intermediates to society.

I will briefly conceptualize this broadened view of technology development. Under conventional schema, the basic movement of technology development transfer can be simply described, and involves three stages.

Stage one begins with research and science which moves by various means to stage two. Here, intermediate parties respond to or develop the science. In a conventional schema, this intermediate is generally industry which develops the science to yield at stage three results. Products or applications with commercial value.

I suggest that this conventional schema is increasingly inadequate to represent the movement and effects of technological development in our age. While accurate enough in its representation of three components; science, industry and products, the schema does not reflect a growing reality; the technology transfer inevitably involves or affects a far greater number of societal components, varied in their nature and far from tidy in their interrelationships. A more comprehensive view of technology transfer is needed to accommodate these varied components.

Under this comprehensive view, there is still movement between three broad stages, but stages two and three are far wider in both participants and results.

Stage one again begins with research and science. As the science develops and is tested, however, it moves to the purview or attention at stage two, not just of industry but of many intermediate parties; corporations, of course, but also governments, public interest groups, individuals, regulators, policymakers and the varied educational, religious and civic components of our society. Varying in agenda and perception, these parties will respond to the science in various ways. For those parties not involved with product development—and most are not—

Stage three will yield a range of other results, generally less tangible in nature, but no less real in impact. For diverse societal, institutional and governmental groups, new science and technology yield diverse implications, problems or needs, including education and training, policy and regulations, ethics and religion, the environment, funding and economic priorities, research priorities and societal issues.

This comprehensive schema for technology transfer is less than clear. It yields not just products on the shelf, but a complicated mixture of questions, imperatives, opinions and issues. As such, this comprehensive schema does more to reflect the reality of our pluralistic society and the positioning of technology within our society.

Under this view, the industrially-developed products that enter stage three are only one of the results of moving science to society. The products must take their place amidst the range of other results, necessarily being judged or affected by them. The products are thus scrutinized and not just for the effectiveness with which they have transferred science to application, but for their fit within the needs and agendae of the many components of society. The product or application might be judged from the vantage points of federal regulations, economic usefulness, environmental impact, religious implications, public uncertainty or national prestige—among just a few. These judgments are not likely to be necessarily scientific in nature; they are even less likely to be in agreement.

At the minimum, societal evaluations of a new scientifically based product or technology can lead researchers and corporations to consternation and annoyance. At the worst, such evaluations can lead to products or perhaps to whole technologies that occasion mistrust, are utilized poorly or not at all, and that do not bring either societal or economic gain.

The collection of techniques and processes called biotechnology furnishes examples of the diverse results and factors that can readily occur when science and technology are transferred from laboratory and corporation to society. I give you three examples:

Expected results from the human genome project and related commercially available new techniques for genetic screening and analysis, have already raised, for instance, enormously complicated issues about insurance, medical coverage and employment practices; questions about the terms under which human beings are defined and evaluated; issues concerning confidentiality, intellectual property rights, access of information and forensic analysis; ethical

questions about rights to procreate; a range of issues and at the point where law, medicine and individual rights converge; and a growing discourse about biological determinism.

Development and field testing of herbicide resistant plants through genetic engineering raises divergent environmental responses, questions about priorities for science research and the suggestion that legislation can resolve thorny issues that appear otherwise intractable.

Moving bovine somatotropin, a protein to increase milk production, from corporate laboratory to public availability has occasioned, among other results, a plethora of aggressively varied opinions; state-based legislation; questions about scale of farming and America's agricultural heritage; issues of corporate responsibility, academic credibility and research priorities; emotional responses; thoughts on the symbolism of milk; and the possibility that large sums invested for research and production of this protein will be slowly, if ever, recaptured.

In these and other cases, the point is clear. Transferring science from idea and laboratory to product and the public, which is after all the goal of technology transfer and technological development, yields a host of non-product results, of issues and implications and opinions. These results can, and in some cases probably should, call into question how that technology or product should best be used. Such attendant non-product results also call into question if the technology or product is ever to be used at all. Common sense suggests that we factor such variables into the process of technology development, for they are just as able as poor research methodology, for instance, to truncate technological development, societal applications and economic gain.

The movement from science to product involves many parties, separated by time, geography and training. Because no one involved individual or organization can be expected to alone assume responsibility for this comprehensive view, doing so must be at least conceptually part of the thinking and repertoire of all involved. If all involved do grant, from the beginning of the process, that their activities might well and probably will create societal results and implications as well as products, a number of practical benefits will be gained.

(1) Participants in technological development will be better able to take an anticipatory rather than a reactive stance to the concerns, issues or doubts directed to their activities, their science and their products.

(2) Participants in technological development will be better prepared for the likelihood that their activities, science and products will not be judged on the basis of science alone.

(3) While each participant in scientific and technological development is not trained or able to address a mixture of cultural, ethical or regulatory issues themselves, they will at least be alert to the likelihood that such issues are part and parcel of the total development process and will be more likely to work earlier in the process with those persons or parties who can address such issues.

(4) Technological development and technology transfer will take place with more attention to a wider range of societal rather than just scientific or industrial objectives. Products or applications will

be more likely understood, accepted and used if developed with realistic attention to the complicated web of values, mores and needs that comprise a society.

Broadening our view of technology development and technology transfer to include attendant issues and needs increases likelihood of an environment conducive to such development, for it more realistically addresses the nature of the total societal environment in which products of science will eventually be used, marketed and purchased.

I encourage this Committee, as well as others involved in science development and science policy, to incorporate this more comprehensive framework into thought activities and policies. Doing so might well yield scientific priorities and scientifically based products that, from the beginning, are more consonant with the needs and expectations of a pluralistic society, and as such simply more accepted by that society. Without such acceptance, full and complete technology transfer will not finally result, nor will societal and economic gain.

Thank you.

[The prepared statement of Mr. Burke follows:]

United States House of Representatives
Subcommittee on Technology and Competitiveness of the
Committee on Science, Space, and Technology

Hearing on Biotechnology and Technology Transfer
Research Triangle Park, NC
6 May 1991

Testimony of W. Steven Burke • Director of Education and Public Affairs, North Carolina Biotechnology Center

Establishing a Favorable Environment for Technology Transfer

Mr. Chairman and Committee Members:

In his earlier testimony, Dr. Charles Hamner, President of the North Carolina Biotechnology Center, furnished committee members introductory information about the Center. I will build on that information, doing so less to explain our activities but more to inform of conclusions we have reached about effective technology transfer and technological development. All of our activities and conclusions have of course been directed to one point – how to assure within North Carolina a framework and environmental favorable for development of a complicated biologically-based technology.

Established in 1981 as the nation's first state-based biotechnology initiative, the Center works to assure that North Carolina gains economic and societal benefit from biotechnology. As there was no blueprint for development of a single new technology throughout a single state, the Center has over time necessarily evolved the approaches and activities with which it encourages the movement of science to commercial products.

The Center's structural approach evolved early. The Center would not itself be a site for research, but would instead fund and catalyze those research universities far better able to explore the science on which biotechnology rests. The Center was constituted as a private non-profit corporation – a neutral entity, able to work with and draw on the varied academic, industrial, governmental, and public parties required for technological development. As such, the Center stands even today in some contrast to other biotechnology agencies, which tend to be research oriented or positioned in a more standard framework.

Other characteristics of the Center – combining philosophical approach with operative structure – followed. Attention to public education and public information was early regarded as central to our task, as soon was attention to business information, public policy, and business development. Varied activities and programs in time mirrored our growing recognition – that we could not assure effective and steady development of biotechnology in North Carolina unless unless we approached it comprehensively. As such, our activities assist at all points in the continuum along which technology develops, beginning with idea and research and ending with products and commercial gain.

We recognized, early and strongly, that this continuum does not operate in a void, but instead within the geography, culture, and 6.3 million people of this state. As such, the Center works earnestly to address the questions and needs that inevitably arise when new science meets ongoing society. We attend to education and training at all levels from middle school to university; we initiated development of consensus state legislation on the environmental release of genetically engineered organisms, legislation drafted by and satisfying industrial,

corporate, and research points of view; and we have worked to identify and respond to the ethical, societal, and policy issues attendant to a technology that deals with life.

Our comprehensive approach and specific activities have proven workable and, we think, useful to North Carolina. While it is gratifying that our our approach has been found worthy of emulation by others involved in biotechnology development nationwide, we are after ten years more pleased that we have necessarily learned a great deal about the development and positioning of a new technology.

Our experience and activities have led us to recognitions about technological development and technology transfer that are relevant to this panel and this hearing. I will concentrate on one of the most significant and over-arching of our conclusions: that technological development in general, and technology transfer in specific, must be seen from the beginning within the fullest possible societal context. Technology transfer can no longer be seen just as a tidy movement from science to industry to application. Technology transfer must be considered, instead, more broadly – as the movement from science to many intermediates to society. Doing so enormously expands the challenges, implications, and potential difficulties of the process.

I will describe this broadened view of technology development and transfer, and suggest how attention to it might prove useful to those working to move science to commercial applications.

Like any transfer, that involving technology results in movement. By a conventional schema, the basic movement of technology can be simply described, and involves three broad stages:

- Stage 1 begins with research and science, which – as we have seen today – moves by various means to
- Stage 2. Here, intermediate parties respond to or develop the science; in a conventional schema, this intermediate is generally industry, which develops the science to yield, at
- Stage 3, results: products or applications with commercial value.

This conventional schema offers tidy shorthand if our emphasis is largely on the interrelationship of universities and corporations, the development of products, and the economic life of society.

I suggest, however, that this conventional schema is increasingly inadequate to represent the movement and effects of technological development in our age. While accurate enough in its representation of three components – science, industry, and products – the schema does not reflect a growing reality: that technology transfer inevitably involves or affects a far greater number of societal components, varied in their nature and far from tidy in their interrelationships. A comprehensive, rather than conventional, view of technology transfer is now needed to accommodate these varied components.

Under this comprehensive view, there is still movement between three broad stages, but stages 2 and 3 are far wider in both participants and results:

- Stage 1, again, begins with research and science. As the science develops and is tested, however, it moves to the purview or attention at

- Stage 2 of not just industry but of *many* intermediate parties: corporations, of course, but also governments, public interest groups, individuals, regulators, policy-makers, and the varied educational, religious, and civic components of our society. Varying in agenda and perception, these parties will respond to the science in various ways. For those parties not involved with product development – and most are not –

- Stage 3 will yield a range of *other* results, generally less tangible in nature but no less real in impact. For diverse societal, institutional, and governmental groups, new science and technology yield diverse implications, problems, or needs, including: education and training, policy and regulations, ethics and religion, the environment, funding and economic priorities, research priorities, and societal issues.

This comprehensive schema for technology transfer and technological development is less clean; it yields not just products on the shelf but a complicated mixture of questions, imperatives, opinions and issues. As such, this comprehensive schema does more reflect the reality of our pluralistic society and the positioning of technology within our society.

Under this broadened view, the industrially-developed products that enter Stage 3 are only one of the results of moving science to society. The products must take their place amidst the range of other results, necessarily being judged by or affected by them. The products are thus scrutinized not just for the effectiveness with which they have transferred science to application, but for their fit within the needs and agendae of the many components of society. The product or application might be judged from the vantage points of federal regulations, economic usefulness, environmental impact, religious implications, public uncertainty, or national prestige – among just a few possibilities. These judgements are not likely to be necessarily scientific in nature; they are even less likely to be in agreement.

At the minimum, societal evaluations of a new scientifically based product or technology can lead researchers and corporations to consternation and annoyance. At the worst, such evaluations can lead to products – or perhaps whole technologies – that occasion mistrust, are utilized poorly or not at all, and that do not bring either societal or economic gain.

The collection of techniques and processes called biotechnology furnishes useful examples of the diverse results and factors that can readily occur when science and technology are transferred from laboratory and corporation into society. Three examples are instructive:

- Expected results from the human genome project, and related commercially available new techniques for genetic screening and analysis, have already raised, for instance: enormously complicated issues about insurance, medical coverage, and employment practices; questions about the terms under which human beings are defined and evaluated; issues concerning confidentiality, intellectual property rights, access of information, and forensic analysis; ethical questions about rights to procreate; a range of issues and at the point where law, medicine, and individual rights converge; and a growing discourse about biological determinism.

- Development and field-testing of herbicide resistant plants through genetic engineering raises divergent environmental responses, questions about

priorities for science research, and the suggestion that legislation can resolve thorny issues that appear otherwise intractable.

- Moving bovine somatotropin, a protein to increase milk production, from corporate laboratory to public availability has occasioned, among other results: a plethora of aggressively varied opinions; state-based legislation; questions about scale of farming and America's agricultural heritage; issues of corporate responsibility, academic credibility, and research priorities; emotional responses; thoughts on the symbolism of milk; and the possibility that large sums invested for research and production of this protein will be slowly, if ever, recaptured.

In these and other cases, the point is clear. Transferring science from idea and laboratory to product and public – which is, after all, the goal of technology transfer and technological development – yields a host of non-product results, of issues and implications and opinions. These results can, and in some cases probably should, call into question how that technology or product should best be used. Such attendant non-product results can also call into question if the technology or product is ever to be used at all. Common sense suggests that we factor such variables into the process of technology development, for they are just as able as poor research methodology, for instance, to truncate technological development, societal applications, and economic gain.

When this happens, science has moved incompletely and ineffectively into society, with the expected steady movement from research to product truncated at the end of the line. The fullest sort of technology transfer has in fact not happened, because science becomes technology only when it addresses tangible needs and yields results or products that are useful *and* used. Since it is clear that varied societal factors *can* in fact limit the use of new scientifically based products and technologies – for reasons that range from the absolutely well-founded to the capricious – it behooves those involved in technology development to attend to these factors from the beginning of the process.

The title of this panel – establishing a receptive *environment* for technology transfer – is thus connotatively important. Environment is defined as that complex of social and cultural conditions affecting the nature of an individual or community. This complex of social and cultural conditions is, clearly, the framework into which technology does or does not fit, and by which it is judged to be acceptable and useful. A receptive environment is one in which the movement from science to technology and product is acceptable and yields useful results. If we grant, as we must, that our total societal environment comprises a complex of issues, conditions, parties, and factors, then it follows obviously that establishing a receptive environment for technology transfer requires attention to this complex web. It is for this reason that a comprehensive view of technology transfer and technology development is both a sound strategy and a societal responsibility.

Taking such a view, as noted earlier, enormously expands the challenges and implications of the process. The movement from science to product involves many parties, separated by time, geography, and training. Because no one involved individual or organization can be expected to alone assume responsibility for this comprehensive view, doing so must be at least conceptually part of the thinking and repertoire of all involved.

If all involved in technology transfer and technology development grant from the *beginning* of the process – from the point of basic research onward – that their activities might create

societal results and implications as well as products, a number of practical benefits will be gained:

1 Participants in technological development will be better able to take an anticipatory rather than reactive stance to the concerns, issues, or doubts directed to their activities and products. Recent examples of societal responses to certain products and technologies well affirm that anticipation serves far better than surprised reaction, annoyance, or inadequate answers to the question of just what scientists and industry had in mind.

2 Participants in technological development will be better prepared for the likelihood that their activities and products will not be judged on the basis of science alone. Excellent science, however effectively developed, is not necessarily assured an immediate place within the nation's economic or societal life.

3 While each participant in scientific and technological development is not trained or able to address a mixture of cultural, ethical, or regulatory issues themselves, they will at least be alert to the likelihood that such issues are part and parcel of the total development process – and will be more likely to work earlier in the process with those persons or parties who can address such issues.

4 Technology development and transfer will take place with more attention to a wider range of societal – rather than just scientific or industrial – objectives. Products or applications will be more likely understood, accepted and used if developed with realistic attention to the complicated web of values, mores, and needs that comprise a society. Such attention, moreover, will assure a public largely untrained in science that scientists do not work in isolation, developing results with more attention to their own research needs than to the larger society.

Broadening our view of technology development and technology transfer to include attendant issues and needs increases likelihood of an environment conducive to such development – for it more realistically addresses the nature of the total societal environment in which the products of science will eventually be used, marketed, and purchased. Such a broadened view cannot readily be imposed by fiat; it will, however, be increasingly considered if the evidence of current issues suggests its strategic usefulness to prepare for comparable future difficulties. Encouraging a more comprehensive framework in which to consider technology transfer will prove beneficial to those working to transfer science from research to public application. I encourage this committee, as well as all others involved in science development and science policy, to incorporate this framework into thought, activities, and policies. Doing so might well yield scientific priorities and scientifically-based products that from the beginning are more consonant with the needs and expectations of a pluralistic society, and as such more accepted by that society. Without such acceptance, full and complete technology transfer will not finally result – and nor will societal and economic gain.

Mr. VALENTINE. Thank you, Mr. Burke. Thank all of you gentlemen.

Mr. Roberson, I know that when others come here seeking information so as to emulate what has been accomplished here over the years, that you give the best advice that you know how, because it is to the advantage of the nation that more institutions of this kind come to fruition. What, except for the talk about the universities—and of course, these are outstanding universities, I do not want to question that at all and they are close together, but there are great universities elsewhere in the nation, maybe not that close together but perhaps so in parts of the country—is the problem with real estate a problem, the inability to find this—a contiguous tract of land the size of this. Because what you have here is about what, five or six thousand acres?

Mr. ROBERSON. Six thousand eight hundred.

Mr. VALENTINE. Six thousand eight hundred acres, and only 60 percent of that developed?

Mr. ROBERSON. Yes, about 4000 developed.

Mr. VALENTINE. What do you say to them?

Mr. ROBERSON. Well first of all, there has been a proliferation of science parks around the country. In 1980, there were about 15. In 1990 there is something like 160. so there has been an enormous growth of science parks around over the country, most are quite small. There are a couple of science parks that are larger than Research Triangle Park but they have not been successful attracting any users.

One of the reasons this park has been successful has been its base cost. As you will recall, Congressman, this land was essentially worn out farm land.

Mr. VALENTINE. I was going to mention that but I have already gone too far back in the horse and buggy age, to say that I remember when you could have bought this land for $50.00 an acre.

Mr. ROBERSON. Yes. There was an awful lot of it bought at that. Of course the values have improved considerably since that point in time. But it would be very difficult to replicate RTP simply because of that base cost in 1959, something like $200.00 an acre. And today, it would be very difficult to find that, certainly within an area that has major universities so close by.

Mr. VALENTINE. Mr. Riley, the licensing that your organization—by the way, is your headquarters, your office in the Park?

Mr. RILEY. Yes, sir.

Mr. VALENTINE. Do you deal just with licenses that resulted from cooperative activities amongst these three universities or do you deal with their individual research?

Mr. RILEY. Individuals.

Mr. VALENTINE. And is there any connection necessarily between the licensing function that you perform and what these universities do in connection with Research Triangle Park? I mean you just do not deal with a license that resulted from a cooperative arrangement—

Mr. RILEY. All of the universities have a similar policy, if a company sponsors research at the university, it more than likely will have a clause in the agreement that says it has something like the first right of refusal or something of that type. Most of the technol-

ogy that we handle is generated by federal grants or some sort of government or agency grant of some sort. And that is where the bulk of the technology comes to us for licensing.

Mr. VALENTINE. But you might be involved in a licensing process or in a licensing effort that resulted from research, that did not have anything to do with the Research Triangle Park.

Mr. RILEY. That is correct. In fact, I would say that the bulk of it would fall in that category, as far as where we get the technology is concerned.

Mr. VALENTINE. Is there a similar licensing consortium serving other universities in this state?

Mr. RILEY. Not in this state that I know of. In fact, I do not think in the country. We are unique in a couple of ways and one of the biggest ways is that I do not know of anyone that services—was created by three universities and services just that group. There are consortia of course. The other thing that makes us unique is I do not know of anyone who has a combination of members that are—you have private and public universities involved here, which makes it really different.

Mr. VALENTINE. You are funded by the universities themselves. Any money from the state or federal government?

Mr. RILEY. Well technically we were set up as a cost center, which the universities would have to pay our costs. But as it turns out, the Triangle Foundation, through TUCASI gave the universities a grant to start—a $1.8 million grant—to cover most of the operating costs for the first five years operation. That was the money to get it going.

Mr. VALENTINE. Mr. Burke, what exists in the NC Biotechnology Center—are there other technology or technological areas which in your judgment would lend themselves to this type of organizational effort on a state-by-state basis or indeed in some method that involved some participation by the federal government, such as microelectronics or indeed, do they exist?

Mr. BURKE. Do other such state-based agencies exist?

Mr. VALENTINE. Yes, dealing with other areas like microelectronics, for example.

Mr. BURKE. With the exception of North Carolina's microelectronics endeavor, I am not aware of any other state that has so comprehensive an approach to either biotechnology or microelectronics development as North Carolina does. I would think that the process of technological development is the same in any place and regardless of the technology. So a comprehensive effort that involves a number of parties in a targeted way should, I think, be emulated in other places for other technologies with comparably effective results.

Mr. VALENTINE. Mr. Rohrabacher.

Mr. ROHRABACHER. Well just a note, I am very impressed with what this represents in terms of your cooperation of government and academic life as well as business. This is really has been an eye-opener for me and I have appreciated your testimony. It is going to give me cause to go back to California and to take a look at what some of our universities are doing and—I want to see if they are doing as much involved in the practical world as what you are involved in. And thank you very much.

Mr. VALENTINE. Thank you, gentlemen.

That brings us to an end. It has been my practice in the past to at the end ask if there is anybody else present who has anything they want to say, but I am not going to say that. The last time I did that, we extended the life of the hearing.

Thank you all very much, thank you all for coming. The Subcommittee is adjourned.

[Whereupon, at 12:45 p.m., the Subcommittee was adjourned.]

APPENDIX

Testimony by

Philip R. Tracy
sident & Chief Executive Officer

Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709

Before the

Subcommittee on Technology and Competitiveness
Committee on Science, Space, and Technology
United States House of Representatives

June 5, 1991

Mr. Chairman and Members of the Subcommittee:

As President and CEO of Burroughs Wellcome Co., I appreciate the opportunity to provide this written testimony about the important process of bringing creative scientific research from the laboratory to the consumer, a process which you have defined as "technology transfer".

We at Burroughs Wellcome Co. are dedicated to the discovery, development, production and marketing of important medicines that improve human health and quality of life. Indeed, as you have described it, "technology transfer" is the essential activity of this research-based pharmaceutical Company. Burroughs Wellcome Co. employs about 4500 people, most of whom live in North Carolina.

We make use of research and development, or "R&D", by investing in the process every day. The process is painstaking and expensive. Successful R&D requires highly skilled, creative thinkers who work in settings supported by significant financial investment over an extended period of time.

It has been estimated that the process of bringing a typical new drug from the bench to the bedside costs an average of $231 million dollars. According to data compiled by the Pharmaceutical Manufacturers' Association from member companies, the U.S. pharmaceutical industry is spending about 17% of total sales on R&D. This is the highest rate of investment in R&D of any domestic industrial group. During our last reported fiscal year, 1989-1990, Burroughs Wellcome Co. and our U.K. parent company, The Wellcome Foundation Ltd, invested about $370 million on basic and medical research and development. Sales of our marketed products must support this investment.

The free market economy in the U.S. encourages risk-taking investment in R&D by rewarding the successes and by protecting intellectual property rights. Today, we shall describe several of our successes in "technology transfer". But, we must not forget that most basic research does not lead directly to a commercially useful product, and that the on-going, privately-funded enterprise of "technology transfer" must be supported by its past successes. We urge this committee to encourage public policy initiatives which inspire the quest for continued innovation in pharmaceuticals.

Since 1988, the private sector U.S. pharmaceutical industry has invested more money in R&D than has been appropriated by Congress for the research budget of the National Institutes of Health. Given present federal fiscal deficits, this trend may well continue. Thus, the U.S. will be relying more upon privately-funded rather than publicly-funded research efforts to accomplish the essential work of "technology transfer" in the development of new medicines. The incentives - and disincentives - which the government proposes for private industry in the next decade will have a profound effect on the continued success of this process.

You have inquired about the sources of research in our field. Most of our Company's basic research data is generated by our own scientists who begin the process of drug development by synthesizing compounds in our Company's laboratories here at Research Triangle Park. We also engage in collaborative research efforts with academic scientists and with government scientists, especially in the testing of new medicines with patients in clinical trials.

We have recently introduced a synthetic lung surfactant, Exosurf® brand Neonatal for Intratracheal Suspension, a product used to treat respiratory distress syndrome, the

most common cause of death and disability among premature infants. The successful development of this vital product is one example of an effective working relationship between scientists and others at Burroughs Wellcome Co. and academic scientists, notably John Clements, M.D., Professor of Pediatrics and a researcher at the University of California - San Francisco, who has devoted his career to basic research on surfactant, the active surface material of the lung. We expect that Exosurf® will save the lives of hundreds of premature newborns every year. This collaborative effort utilizing all of our different areas of expertise and prompt consideration by the FDA accomplished a rapid "technology transfer" for the public good as well as our own scientific success.

About 80% of drugs in use today are synthetic organic chemicals. Burroughs Wellcome Co. scientists synthesize more than 2,000 new compounds each year. Only about one in 5,000 such compounds on average will survive the rigorous testing to become a new drug. Today, it usually takes from seven to ten years to bring a drug from the bench to the bedside. We think that shortening the time period during which "technology transfer" occurs can promote innovation and thereby enhance the international competitiveness of this U.S. industry.

By focusing upon the issue of "technology transfer", it is clear to us that this Committee realizes that the fruits of scientific research must be developed efficiently and be brought promptly to the marketplace, without undue risk to the public health.

Burroughs Wellcome Co. has made major contributions to medicine in its 85-year research history in the United States. Our scientists have shared with the world a unique perspective on making the process of discovering new medicines more efficient.

Some of the most important products of the last three decades originate from a research concept developed by Wellcome scientist emeritus George Hitchings, Ph.D. and his co-worker, Gertrude Elion, Ph.D. When their careers began at Burroughs Wellcome Co. in the 1940s, drug research was still largely a matter of trial and error. Chemists randomly chose or made chemicals to test against a disease-causing organism, or they altered effective compounds to try to make drugs more potent or less toxic.

The new approach was to <u>design</u> molecules that would have a desired action based upon their structure. This revolutionary idea, and the 32-year collaboration that

proved its value by yielding major new drugs, was formally acknowledged by the scientific community in 1988 when Dr. Hitchings and Dr. Elion were awarded The Nobel Prize in Medicine.

The early Hitchings-Elion research was based upon studies of nucleic acids, the building blocks of DNA. Their first success was Purinethol® brand mercaptopurine, one of the first effective anticancer drugs. Later, they discovered agents active against malaria and smallpox.

In 1956, they synthesized trimethoprim, one of the active agents in Septra® brand, a broad-spectrum antibiotic used to treat ear, respiratory and urinary tract infections. Today, this drug is also frequently used in the treatment and prophylaxis of Pneumocystis carinii pneumonia, the most common opportunistic pathogen affecting HIV-infected persons. The Hitchings-Elion discoveries continued with Imuran®, a drug that suppresses the immune system response to prevent organ transplant rejection. Synthesized in 1957, Imuran® brand made organ transplants possible and ushered in our current technology in kidney and heart transplants. Today, Imuran® also is used to treat severe rheumatoid arthritis.

This pioneering strategy is important because it established a more rational approach to drug discovery and combined the principles of chemistry with knowledge about the biology of disease. Today, Burroughs Wellcome Co. scientists working at Research Triangle Park are applying this paradigm augmented by computer-generated imaging in their basic and targeted research in many therapeutic areas including antiviral, anticancer, psychotropic, antibacterial and cardiovascular research.

In the 1980s, Burroughs Wellcome Co. emerged as a leader in antiviral research. In 1982, Wellcome introduced Zovirax® brand, the first effective treatment for genital herpes. The synthesis of Zovirax® at our Research Triangle Park laboratories in 1974 opened a new era in antiviral research. Nontoxic antivirals had not been developed for major viral diseases. Zovirax® blocked replication of the herpes virus and halted infection. It was the first selective antiviral that attacked the virus without substantially harming healthy cells.

In 1987, Wellcome introduced the first drug for the treatment of AIDS, Retrovir® brand zidovudine (commonly called AZT). Retrovir® can prolong the lives of people with AIDS. In persons with early HIV infection who are

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asymptomatic or have minimal symptoms of disease, studies show the drug can prevent the progression of the disease. We are continuing an active R&D program with this drug and other compounds which may prove effective in the battle against AIDS.

Burroughs Wellcome Co. scientists first conceived of the use of AZT to treat HIV infection. We were able to develop this important drug for patient use in only two years through the mobilization of company-wide resources while working in cooperation with scientists and others from academia, the National Institutes of Health, and the U.S. Food and Drug Administration.

Recently, however, the NIH issued an official public statement claiming that certain of its scientists who had collaborated several years ago with the Burroughs Wellcome Co. development effort for Retrovir® ought to have been named as inventors on the Company's patents. The statement further indicated that it was the intention of the NIH to cause the price of this drug to be reduced by assisting a generic manufacturer to invalidate Burroughs Wellcome Co. patents in certain pending legal proceedings initiated as a consequence of that manufacturer's application with the FDA to market a generic copy of the Burroughs Wellcome Co. product.

We think that an important issue in the development of sound public policy on "technology transfer" is to encourage the pharmaceutical industry's traditional emphasis on new drug innovation. It is that emphasis which has led to the development over the years of new drugs and vaccines that have resulted in the prevention of diseases that at one time were major causes of death, and the successful treatment of many others.

We are concerned that attempts to control pharmaceutical prices will have a chilling effect on the future development of new drugs, and that the reluctance of government entities to preserve trade secrets may discourage some private sector/public sector collaborations.

We recognize that the AIDS epidemic has affected our society on many levels and that the reactions of both private and public institutions to the challenge of this terrible disease have evoked controversy. Burroughs Wellcome Co. has become a focal point for the broader social concern of adequate patient access to new drug therapies, but we remain confident in the quality of our past contributions to the process of getting new medicines into the marketplace as we prepare to continue our endeavors in the future.

Part of the continuing work in the discovery of new compounds and to insure the full transfer of important medical discoveries to useful products, is the responsibility to inform physicians and other health care providers about the appropriate use of a new product or new indications for an existing product, such as those recently obtained for Retrovir®. Burroughs Wellcome Co. has been a leader in quality education on HIV infection, AIDS, and appropriate therapies. Burroughs Wellcome Co. undertook to assemble experts in over a dozen of the cities hardest hit by AIDS to develop a comprehensive Treatment Team Handbook, now a standard reference for physicians treating HIV infection. In our industry, the process of "technology transfer" includes a continuous effort to gather information about all our products and to share useful data with healthcare professionals.

One important question before this Committee might be: What is the proper role for the federal government to assure that quality medicines continue to be discovered and developed in this country? It has been reported that the Office of Technology Assessment is conducting a study on "Government Policies and Pharmaceutical Research and Development." It is considering R&D investment, costs, technology, regulations, products liability, tax and

investment policies, and animal research. They are considering analysis of the international aspects of research and regulation and the cost of various resources (i.e., highly-trained personnal, environmental issues, etc.). The process of "technology transfer" within the context of pharmaceutical product development is complex, in part because of the degree of interest in and regulation of the process by the federal government.

Each of these OTA areas of study could merit lengthy testimony. What is important for the public to know is that U.S. government policies may either help or hinder within each area.

For example, congress has passed three incentives that have encouraged R&D activity: the Orphan Drug law, the R&D tax credit, and the possessions credit (commonly referred to as the Puerto Rico 936 provision).

All three laws are now threatened with hostile amendments or outright repeal by those in Congress who have called them "subsidies" rather than "incentives". We would urge members of this Committee not to approve any change in these laws. In fact, we would encourage you to support making the R&D tax credit permanent.

Of course, no new drug travels from chemical synthesis to a prescription for a person without the approval of the U.S. Food and Drug Administration. The ability of the dedicated employees of this Agency to do its vital work efficiently may have been impaired by lack of adequate funding. The Congress could do few things more important than to appropriate sufficient funds for this Agency. If all of us want to see more medicines on the market sooner while maintaining scientifically appropriate standards for safety and efficacy, new resources must be provided to the FDA. There is almost universal agreement that given adequate resources the FDA could more efficiently contribute to the process of "technology transfer" by expediting the drug review and approval process.

We at Burroughs Wellcome Co. have assisted in the initiation of the Treatment IND procedure at FDA, as a means both to improve the efficiency of the new drug approval process and to provide seriously ill patients with greater access to experimental medicines.

We can summarize our concerns:

First, to assure continued successful "technology transfer"; that is, to continue the efficient movement of

creative science from the laboratory to the patient/consumer, the pharmaceutical industry needs predictable and stable fiscal policies. When it takes a decade to bring a drug to market, government cannot change tax obligations or other regulations yearly and expect no negative effects upon the efficiency of the process of new drug development. As to the regulatory process itself, we urge you to support effective funding of the FDA.

Second, if the pharmaceutical industry in the United States is to retain its international leadership in innovative research, the federal government must refrain from legislation that attempts to control pharmaceutical prices such as last year's Medicaid Rebate Law. Instead, the Congress should enact policies that provide incentives for continued research, such as the R&D tax credit.

Third, because our industry is one which requires a highly skilled and well-educated workforce, we especially urge you to support legislation designed to increase the competence of our student population in the natural sciences and mathematics. We applaud this Committee's recognition of the importance of science to the economic future of the United States.

Thank you.

45-340 (160)